FOR PUBLICATON

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S., LLC, Plaintiff, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et. al., Defendants.	Civil Action No. 21-00634 (FLW) **OPINION**
NOVO NORDISK INC., Plaintiff, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et. al., Defendants.	Civil Action No. 21-00806 (FLW)

WOLFSON, Chief Judge:

Plaintiffs Sanofi-Aventis U.S., LLC, and Novo Nordisk Inc.[1] sue the United States Department of Health and Human Services ("HHS"), former HHS Secretary Alex M. Azar II, former HHS General Counsel Robert P. Charrow, Acting HHS Secretary Norris Cochran, Acting HHS General Counsel Daniel J. Berry, the Health Resources and Services Administration ("HRSA"), former HRSA Administrator Thomas J. Engels, and Acting HRSA Administrator

1 Because this Opinion resolves the pretrial motions in both above-captioned cases, where Sanofi and Novo make overlapping arguments, I refer to them jointly as "Plaintiffs." I also refer to HHS and HRSA as "the Government" or simply "HHS."

Diana Esposito (collectively, "the Government") for agency action relating to "the 340B Program," a drug-purchasing provision in the Veterans Health Care Act, Pub. L. No. 102-585, 106 Stat. 4943, 4967-71 (1992), codified at the Public Health Services Act, Pub. L. No. 78-410, 58 Stat. 682 (1992); 42 U.S.C. § 256b.

In 1992, Congress enacted the 340B Program to guarantee prescription drug discounts for medically vulnerable populations and to enable providers in underserved areas to maximize their resources by purchasing drugs from participating manufacturers at the discounted rate. Because most 340B providers cannot afford an in-house pharmacy, or serve large geographical areas where travel is unfeasible or cost-prohibitive, HHS has long interpreted the statute to require manufacturers to ship orders directly to contract pharmacies, such as CVS or Walgreens, which dispense covered drugs to 340B-eligible patients. Contract pharmacies now number in the tens of thousands. Seeking to limit these arrangements for the first time in 2020, manufacturers, including Plaintiffs, implemented various policies. HHS has taken enforcement action in response.

Sanofi challenges three agency actions arising in this context: a 2021 Violation Letter in which HHS threatened to impose Civil Monetary Penalties ("CMPs") on Sanofi for overcharging for drugs through its policy, called an "Integrity Initiative,"[2] a 2020 Advisory Opinion ("AO") interpreting § 340B to require Sanofi to ship drugs to multiple contract pharmacies, and a 2010 Administrative Dispute Resolution Rule ("ADR Rule") designed to adjudicate claims arising under § 340B. According to Sanofi, its Integrity Initiative fully complies with the 340B Program, the AO is arbitrary and capricious under the Administrative Procedures Act ("APA"), 5 U.S.C. § 500 *et*

2 During the pendency of these cases, HHS referred Plaintiffs to the Office of the Inspector General ("OIG") for sanctions, though the OIG has not yet imposed any. *See, e.g.*, HRSA, Updated Letter to Sanofi Regarding Sales to Covered Entities through Contract Pharmacy Arrangements, at 1 (Sept. 22, 2021), *available at* https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/updated-hrsa-letter-sanofi-covered-entities.pdf (last visited Nov. 4, 2021). Plaintiffs have requested an expedited ruling on this basis. *See, e.g.*, No. 21-634, ECF No. 96.

seq., and the ADR Rule is both unconstitutional and arbitrary/capricious. Novo challenges the AO and the Violation Letter on similar grounds, but it does not challenge the ADR Rule. Plaintiffs and the Government cross-move for summary judgment on all issues. For the following reasons, I **DENY** Sanofi's motion as to the ADR Rule and **GRANT** HHS' motion on the same; **GRANT in part** Sanofi's and Novo's motions as to the Violation Letters, and **PARTIALLY VACATE** and **REMAND** the Letters for further consideration, consistent with this Opinion; and **DENY** the parties' motions on the AO as moot.

I. FACTUAL BACKGROUND AND PROCEDURAL HISTORY

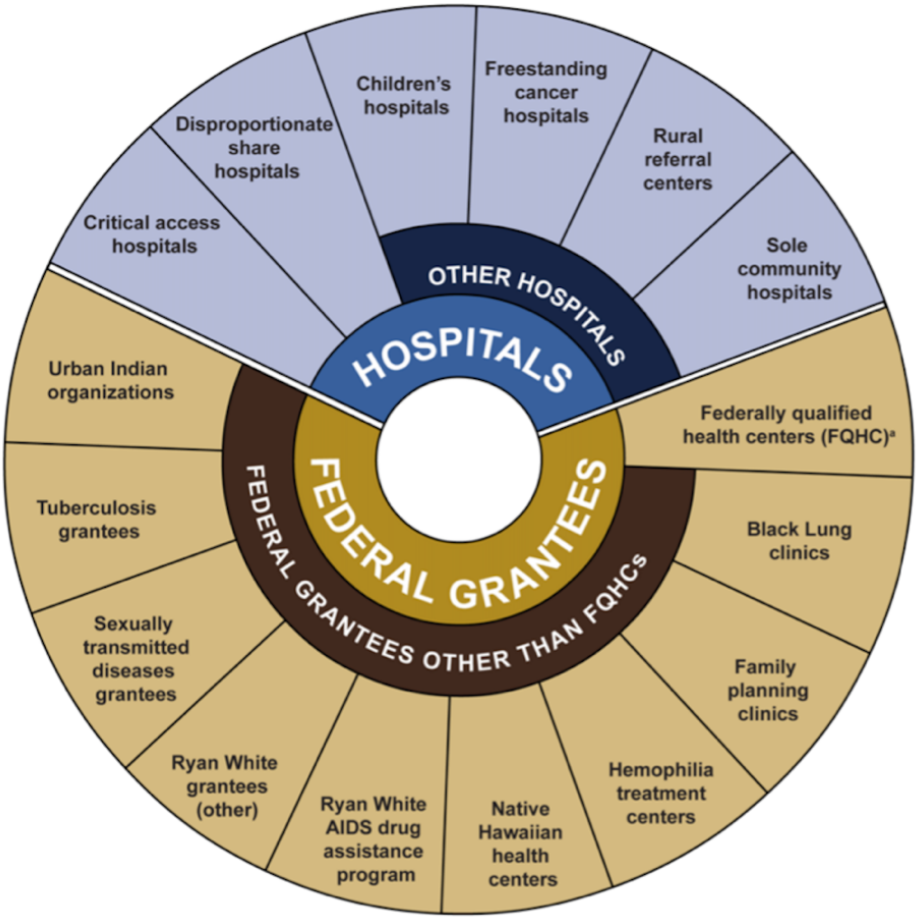
A. Statutory Framework

This case involves the 340B Program, which Congress created thirty years ago to provide certain hospitals and clinics, known as "covered entities," with prescription drugs at or below a heavily discounted rate, called the statutory ceiling price. 42 U.S.C. §§ 256b(a)(1), (4). All parties agree that the relevant statutory language reads:

> The Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid . . . to the manufacturer for covered outpatient drugs . . . purchased by a covered entity . . . does not exceed an amount equal to the average manufacturer drug price for the drug . . . in the preceding calendar quarter, reduced by the rebate percentage described in paragraph (2). Each such agreement . . . shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.

Id. § 256(a)(1).[3] Covered entities include various federally funded health centers serving native and tribal populations, community hospitals serving low-income or rural areas, and specialized clinics. *Id.* §§ 256b(a)(4)(A)-(O). A complete chart, provided by the Government Accountability Office ("GAO"), is appended below.

3 Covered outpatient drug "has the meaning set forth in section 1927(k) of the [Social Security Act]." 42 C.F.R. § 10.3; 42 U.S.C. § 1396r-8(k)(2)(A)(i)-(iii) (codifying § 1927(k)).



GAO Report, No. 18-480. Only Congress may expand the list of covered entities, as it has done several times since 1992, most recently in 2010. *Pharm. Rsch. & Mfrs. of Am. v. Dep't of Health and Hum. Servs.*, 43 F. Supp. 3d 28, 31-32 (D.D.C. 2014). Under the statute, covered entities may not request duplicate discounts or rebates, *i.e.*, a 340B discount and a Medicaid rebate. 42 U.S.C. § 256b(a)(5)(A). Covered entities also may not engage in drug diversion, which is defined as "resell[ing] or otherwise transfer[ring]" a covered outpatient drug "to a person who is not a patient of the entity." *Id.* § 256b(a)(5)(B).

The 340B Program operates through standardized form contracts with HHS, known as Pharmaceutical Pricing Agreements ("PPAs"), which recite the obligations in § 340B and set out terms identical to those contained in the statute. 42 U.S.C. §§ 1396r-8(a)(1)-(5). When a

manufacturer signs a PPA, as it must do to opt into the 340B Program, it agrees to "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." *Id.* § 256b(a)(1). The ceiling price is much lower than the market price—in some cases as little as one penny per pill.[4] 82 Fed. Reg. 1,210, 1,215 & n.1 (Jan. 5, 2017) (estimating discounts between 25 and 50 percent on average).[5] The price is protected from public view by statute and HHS is prohibited from disclosing it in all but a few instances. 42 U.S.C. § 1396r-8(b)(3)(D). The terms of a PPA are not otherwise negotiated or bargained for. *Astra USA, Inc. v. Santa Clara Cty., Cal.*, 563 U.S. 110, 113 (2011). The government may terminate a PPA if it finds that a manufacturer has knowingly and intentionally overcharged a covered entity or has otherwise failed to comply with § 340B. *Id.* § 1396r-8(b)(4)(B)(v); 61 Fed. Reg. 65,406, 65,412-13 (Dec. 12, 1996).[6] In the alternative, the government may impose a CMP on any manufacturer who knowingly and intentionally overcharges a covered entity, up to $5,000 per overcharge. 42 U.S.C. § 256b(d)(1)(B)(i)(IV); 82 Fed. Reg. at 1,228 (defining, in part, the statutory terms "overcharge" and "knowingly and intentionally").

According to Congress, the 340B Program has dual benefits: "enable [covered] entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services," and ensure affordable prescriptions for the

4 The § 340B ceiling price applies the methodology manufacturers use to determine their "average" and "best" price under the closely related, and earlier enacted, Medicaid Drug Rebate Program. 42 U.S.C. §§ 1386r-8(c), (k). "Calculation of that price is a complex enterprise requiring recourse to detailed internal information about a company's sales and pricing practices." *Astra*, 563 U.S. at 110; 42 U.S.C. § 1396r-8(k); 42 C.F.R. § 447.500-520. Additionally, the 340B Program covers over-the-counter medications for which there are no Medicaid rebates. 42 U.S.C. § 256b(a)(2)(B). For such drugs, § 340B prescribes a substitute calculation method. *Id.* § 256b(a)(2)(B)(i).

5 Ceiling Price and Manufacturer Civil Monetary Penalties Regulation.

6 Manufacturer Audit Guidelines and Dispute Resolution Process Regulation.

uninsured/underinsured.[7] H.R. Rep. No. 102-384, pt. 2, at 12 (1992). Likewise, as the GAO recently found, "providers have used the benefit made available through the drug discounts to provide critical health care services to communities with underserved populations that could not otherwise afford [such] services—for instance, by increasing service locations, developing patient education programs, and providing translation and transportation services." Am. Hosp. Ass'n, et. al., Amici, at 3 (quoting GAO Report, No. 11-836)[8]; Nat'l Ass'n of Comm. Health Ctrs., et al., Amici, at 15-20.[9]

Congress conditioned manufacturers' eligibility for Medicare Part B and Medicaid, two of the nation's largest health insurance programs,[10] on participation in § 340B. 42 U.S.C. § 1396r-8(a)(1). If a manufacturer declines to opt into the 340B Program by signing a PPA with HHS, or runs afoul of its statutory obligations, it risks losing billions of dollars and a "significant portion

---

7 In enacting the 340B Program, Congress responded to an increase in prescription drug prices for the Department of Veterans Affairs and other federally funded clinics and public hospitals following the Medicaid Drug Rebate Program.

8 The American Hospital Association is an industry trade group with approximately 5,000 members, many of whom use the 340B Program. Six other hospital/healthcare associations have joined its brief. The Magistrate Judge Granted the Motion to File Amici Curiae on September 28, 2021. No. 21-634, ECF No. 98.

9 The National Association of Community Health Centers ("NACH") is a nonprofit organization with a national membership of federally funded clinics, known as federally qualified health centers, which provide care to approximately one in twelve Americans. No. 21-806, ECF No. 56, at 3. 82 percent of those patients are uninsured/underinsured. *Id.* at 4. NACH has filed a motion seeking amici status, which I grant. *Bryant v. N.J. Dep't of Transp.*, 987 F. Supp. 343, 346 n.3 (D.N.J. 1998) (holding that district courts have "broad discretion" to determine the "extent, if any, to which an amicus curiae should be permitted to participate in a pending action"); *United States v. Alkaabi*, 223 F. Supp. 2d 583, 592 (D.N.J. 2002) (stating reasons for which a court can grant an amici's motion, including timely and useful information).

10 In 1992, about 29 million people enrolled in Medicaid at a cost of $120 billion. In 2018, more than 76 million people enrolled at a cost of $616 billion. Medicaid and CHIP Payment and Access Commission, MACStats: Medicaid and CHIP Data Book, at 27-28 (Dec. 2019), *available at* https://www.macpac.gov/wp-content/uploads/2020/01/MACStats-Medicaid-and-CHIP-Data-Book-December-2019.pdf (last visited Nov. 4, 2021). Thus, technically speaking, while Plaintiffs are free to opt out of the 340B Program, doing so may not be financially feasible.

of [ ] annual revenue." Am. Compl., ¶ 28. The 340B Program is considered essential to the country's safety net system for medically vulnerable populations, many more patients rely on it today than in 1992, and it is growing every year. For example, covered entities purchased $12 billion in discounted drugs in 2015, saving approximately $6 billion.[11] Such sales comprised about three percent of the entire U.S. prescription drug market.[12] By 2018, the number of hospitals and associated sites had increased by 3,000 percent compared to 2005, to 2,541 hospitals and 26,641 sites.[13] 743 manufacturers and 12,722 covered entities participated in all,[14] while discounted drug purchases reached $24 billion that year.[15] The 340B Program is estimated to encompass 40 percent of all U.S. hospitals today and 14 percent of all branded outpatient drug sales, and it is the second largest drug purchasing program behind Medicare Part D. Vandervelde Amici, at 7-8.[16] "[A]lmost half the U.S. pharmacy industry now profits,"[17] and according to a recent report, drug sales topped

---

11 House Energy and Commerce Committee, Review of the 340B Drug Pricing Program, at 11-13 (Jan. 10, 2018), *available at* https://republicans-energycommerce.house.gov/wp-content/uploads/2018/01/20180110Review_of_the_340B_Drug_Pricing_Program.pdf (last visited Nov. 4, 2021).

12 82 Fed. Reg. at 1,227 & n.1.

13 House Energy and Commerce Committee, Walden and Alexander Ask for Input on Modernizing 340B Drug Pricing Program (Oct. 2020), *available at* https://republicans-energycommerce.house.gov/news/walden-and-alexander-ask-for-input-on-modernizing-340b-drug-pricing-program/ (last visited Nov. 4, 2021).

14 *Supra*, note 11, at 12.

15 FY 2021 Budget, Dep't of Health and Human Servs., at 36 (Oct. 2020), *available at* https://www.hhs.gov/sites/default/files/fy-2021-budget-in-brief.pdf (last visited Nov. 4, 2021).

16 Aaron Vandervelde is the Managing Director at Berkeley Research Group, LLC. He currently licenses software he developed to Sanofi for use in its Integrity Initiative. He purports to take no position on the legal issues in this case. The Magistrate Judge granted his motion to appear amicus curiae on September 28, 2021. No. 21-634, ECF No. 97.

17 Adam J. Fein, The Federal Program That Keeps Insulin Prices High, WALL. ST. J. (Sept. 10, 2020), *available at* https://www.wsj.com/articles/the-federal-program-that-keeps-insulin-prices-high-11599779400 (last visited Nov. 4, 2021).

$38 billion in 2020, up 27 percent over 2019 and quadruple the amount in 2014.[18] At the same time, though these numbers appear large, it is important to put them in context. Between 2010 and 2018, the pharmaceutical industry as a whole generated $8.6 trillion in profit. Am. Hosp. Ass'n, et al., Amici, at 5 & n.3 (citation omitted).

B. Guidance History

The present dispute centers on "contract pharmacies," which partner with covered entities to dispense 340B-priced drugs off-site. To date, HHS has issued two non-binding guidance documents authorizing covered entities to use contract pharmacy arrangements.

i. The 1996 Guidance

HHS issued the first guidance document in 1996, after "it became apparent that only a very small number of the 11,500 covered entities used in-house pharmacies (approximately 500) . . . . including many of the larger groups of covered entities" such as "community and migrant health centers, hemophilia clinics, and most of the Ryan White HIV service programs." 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996) ("the 1996 Guidance"). According to the 1996 Guidance:

> It has been the Department's position that if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price. **If the entity directs the drug shipment to its contract pharmacy, we see no basis on which to conclude that section 340B precludes this type of transaction** or otherwise exempts the manufacturer from statutory compliance.

Id. at 43,549 (emphasis added). The Guidance further explains:

> It would defeat the purpose of the 340B program if [ ] covered entities could not use their affiliated pharmacies in order to participate. Otherwise, they would be faced with the untenable dilemma of having either to expend precious resources to develop their own in-house pharmacies (which for many would be impossible) or

18 Adam J. Fein, *Exclusive:* The 340B Program Soared to $38 Billion in 2020—Up 27% vs. 2019, Drug Channels (June 16, 2021) (obtaining data through Freedom of Information Act), *available at* https://www.drugchannels.net/2021/06/exclusive-340b-program-soared-to-38.html (last visited Nov. 4, 2021).

> forego participation in the program altogether. Neither option is within the interest of the covered entities, the patients they serve, or is consistent with the intent of the law.

Id. at 43,550. Despite interpreting § 340 broadly in this sense, HHS limited covered entities to one contract pharmacy each, though it expressly indicated that it was considering whether to make the 340B Program available to multiple contract pharmacy sites in the future. *Id.* at 43,555 ("[The agency] will be evaluating the feasibility of permitting [ ] covered entities to contract with more than one site.").

ii. The 2010 Guidance

HHS issued another non-binding guidance document on contract pharmacy arrangements in 2010. 75 Fed. Reg. 10,272 (Mar. 5, 2010) ("the 2010 Guidance"). The 2010 Guidance clarified that covered entities may use multiple contract pharmacies, contingent on five requirements. *Id.* at 10,277 ("In addition to contracting with a single pharmacy for each clinical site, covered entities may pursue more complex arrangements that include multiple pharmacies."). HHS reasoned that "[i]t would be a significant benefit to patients to allow the use of more easily accessible, multiple contract pharmacy arrangements by covered entities" and that, because "some patients currently face transportation barriers or other obstacles that limit their ability to fill their prescriptions," multiple sites "would permit covered entities to more effectively utilize the 340B program and create wider patient access." *Id.* at 10,273. HHS included "essential elements" in the 2010 Guidance to prevent drug diversion and duplicate discounting. For example, a "covered entity will purchase the drug, maintain title to the drug and assume responsibility for establishing its price"; "[a] 'ship to, bill to' procedure [will be] used in which the covered entity purchases the drug; the manufacturer/wholesaler must bill the covered entity . . . but ships the drug directly to the contract pharmacy"; "[b]oth the covered entity and the contract pharmacy are aware of the potential for

civil or criminal penalties" for violations; and both must maintain auditable records, track prescriptions, and verify patient eligibility. *Id.* at 10,278.

Partly as a result of the 2010 Guidance, contract pharmacy sites grew from 1,300 to about 20,000 in 2017.[19] The five largest community/retail drug chains in the United States—CVS, Walgreens, Walmart, Rite-Aid, and Kroger—make up 60 percent of all contract pharmacies but just 35 percent of pharmacies nationwide,[20] and approximately one-third of all covered entities currently use contract pharmacy arrangements,[21] ranging from 1 to 439 per covered entity, with an average of 12.[22] While about half of all covered entities and their contract pharmacies are located within 30 miles of each other, and the median distance is 4 miles, 45 percent of disproportionate share hospitals, who serve predominantly low-income patients, use at least one contract pharmacy more than 1,000 miles away.[23] According to a recent report, contract pharmacies account for approximately 30 percent of the entire 340B Program.[24]

C. Sanofi's Integrity Initiative

For a decade, every manufacturer participating in the 340B Program complied with the 2010 Guidance by shipping drugs to designated contract pharmacies whenever and wherever requested. That changed on October 1, 2020, when Sanofi announced its Integrity Initiative in an

---

19 GAO, Report No. 18-480, Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, at 10 (June 21, 2018), *available at* https://www.gao.gov/assets/gao-18-480.pdf (last visited Nov. 4, 2021). However, since the same pharmacy may have a contract to work with multiple covered entities, the number of contract pharmacy arrangements stated here is likely more than the number of pharmacies that actually dispense 340B drugs. *Id.* at 20 n.32.

20 *Id.* at 21.

21 *Id.* at 16.

22 *Id.* at 18.

23 *Id.* at 22-23.

24 *Supra*, note 19.

apparent effort to prevent duplicate discounting and drug diversion. Sanofi's move followed a July 2020 notice from Eli Lilly that it would not offer 340B pricing through contract pharmacy arrangements for Cialis, its popular erectile dysfunction drug. Eli Lilly extended its notice to all covered drugs one month later, with certain caveats/exceptions, and AstraZeneca imposed similar restrictions around the same time.

The gist of the Integrity Initiative is that covered entities must submit claims-level data for 340B-priced drugs dispensed by contract pharmacies with which they partner, or else they cannot use multiple contract pharmacies. Sanofi requires covered entities to register with a third-party data-sharing platform as part of its initiative, designed by amici Vandervelde. Sanofi informed HHS that, "if a covered entity refuses to provide the claims data described above, [it] will restrict the entity's use of contract pharmacy arrangements." At the same time, Sanofi announced that a covered entity without an in-house pharmacy could designate a single contract pharmacy to receive 340B-priced drugs, regardless of whether the covered entity provides the requisite data. Under its initiative, Sanofi explains, it offers 340B-priced drugs in three ways: (1) through the covered entity's own in-house pharmacy, (2) through a single, designated contract pharmacy, if the covered entity has no in-house pharmacy but cannot or does not wish to provide claims-level data, and (3) through multiple contract pharmacies, if the covered entity provides the data Sanofi requests.

D. Novo's Policy

Novo imposed a similar, but less involved, policy around the same time as Sanofi. "If a covered entity does not have an in-house pharmacy, Novo will allow the covered entity to designate a single outside pharmacy to dispense the drug to the covered entity's patients, and Novo will facilitate shipment to that single contract pharmacy. But Novo is no longer willing to facilitate the transfer of its drugs to an unlimited number of commercial pharmacies; nor is it willing to

facilitate their extra-statutory participation in the program." Novo Br., at 12. In this sense, Novo states, its "policy returns to the approach that applied for the 14 years between 1996 and 2010." *Id.* Novo will also "continue—as it has under the 2010 Guidance—to voluntarily ship[] drugs to [multiple] contract pharmacies in its discretion in situations where risks of abuse are less significant." *Id.* at 21. As it stands, Novo has halted 340B shipments predominantly to contract pharmacies associated with hospitals, while continuing to complete orders from federal grantees and sub-grantees.

In response to these measures, covered entities filed emergency motions for injunctive relief. HHS moved to dismiss the suits for lack of jurisdiction, while confirming an ongoing investigation into the manufacturers. Courts agreed with HHS that "[the judiciary's] role comes only after the parties have participated in [the] ADR process," and "Congress made explicit that alleged 340B Program violations are to be first adjudicated by HHS." *Am. Hosp. Ass'n v. Dep't of Health & Human Servs.*, No. 20-08806, 2021 WL 616323, at *6 (N.D. Cal. Feb. 17, 2021) (declining to "short-circuit the foundational regime that Congress has enacted in the 340B Program"); *Astra*, 563 U.S. at 113 ("[S]uits by 340B entities to enforce ceiling-price contracts running between drug manufacturers and the Secretary of HHS are incompatible with the statutory regime."). According to HHS, it has since taken certain actions—the subject of these suits—to curb Plaintiffs' self-help efforts, which the agency believes are fundamentally opposed to the statutory scheme.

E. Challenged Agency Actions

Sanofi now challenges three agency actions relating to the 340B Program: (1) the AO on contract pharmacy arrangements, (2) the ADR Rule setting forth mandatory procedures for adjudicating § 340B disputes, and (3) the Violation Letter in which HHS threatened Sanofi with

CMPs for its Integrity Initiative. Novo challenges the AO and the Violation Letter with respect to its policy, but not the ADR Rule. At no point before this suit has any manufacturer disputed how HHS administers or interprets the 340B statute.

i. The Advisory Opinion

On December 30, 2020, HHS' General Counsel issued an AO concluding that "covered entities under the 340B Program are entitled to purchase covered outpatient drugs at no more than the 340B ceiling price – and manufacturers are required to offer covered outpatient drugs [to covered entities] at no more than the 340B ceiling price – even if those covered entities use contract pharmacies to aid in distributing those drugs to their patients." AO 20-06, at 8.[25] HHS reasoned that "the core requirement of the 340B statute . . . is that manufacturers must 'offer' covered outpatient drugs at or below the ceiling price for 'purchase by' covered entities," a "fundamental" component of the statute that "is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs." *Id.* at 2. In HHS' view, the "plain meaning" of § 340 compelled its interpretation. *Id.* at 2-3.

Plaintiffs brought suits contending that the AO was arbitrary and capricious under the APA because it was not the only permissible construction of § 340B. *See, e.g.*, *AstraZeneca Pharms. LP v. Becerra*, No. 21-27 (D. Del. Jan. 12, 2021); *Eli Lilly and Co. et al. v. Becerra*, No. 21-81 (S.D. Ind. Jan. 12, 2021); *Sanofi-Aventis U.S. LLC v. HHS et al.*, No. 21-634 (D.N.J. Jan. 12, 2021); *Novo Nordisk Inc. et al. v. Azar*, No. 21-806 (D.N.J. Jan. 15, 2021); *PhRMA v. Cochran*, No. 21-198 (D. Md. Jan. 22, 2021). The Hon. Leonard P. Stark, U.S.D.J., agreed with the plaintiffs in *AstraZeneca Pharms. LP v. Becerra*, No. 21-27, 2021 WL 2458063 (D. Del. June 16, 2021). First, the court explained its "role" was "to decide only the narrow question[]" whether "the

25 HHS, AO 20-06 (Dec 30, 2020), *available at* https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/340B-AO-FINAL-12-30-2020_0.pdf (last visited Nov. 4, 2021).

position outlined in the [AO] [was] *compelled* by the unambiguous text of the 340B statute." 2021 WL 2458063, at *1 (emphasis added). It did not determine who had the better view of the statute or apply any common forms of agency deference. In answering the question as defined, the court interpreted the AO as "materially different from [HHS's] 1996 and 2010 guidance," in both its bottom line and "mode of analysis," and found that the AO "wrongly determine[d] that purportedly unambiguous statutory language mandate[d] [its] conclusion." *Id.* at *5, *8 (some alterations omitted). The Delaware court nevertheless observed that "HHS' [ ] interpretation of [§ 340B] is permissible" as well as "plausible." *Id.* at *8 n.14, *11. The court further noted that, had HHS interpreted the statute in the manner proposed by AstraZeneca (*i.e.*, to not permit HHS to require manufacturers to ship their drugs to any contract pharmacies), "covered entities would have brought their own suit . . . . [and] the case outcome would have been the same . . . , because the statutory language does not speak to covered entities' use of contract pharmacies." *Id.* at *11.

After *AstraZeneca*, HHS withdrew the AO "in the interests of avoiding confusion and unnecessary litigation," though it noted its disagreement with the proposition that it "intended to impose new, binding obligations on regulated entities" rather than obligations which had always existed under the 340B statute. No. 21-634, ECF No. 90. The Delaware court subsequently entered summary judgment and vacated the AO. *AstraZeneca Pharms. v. Becerra*, No. 21-27, ECF No. 83 (D. Del. June 30, 2021).[26] HHS has ceased all enforcement under the AO, but has stated that withdrawing it does not impact the Violation Letters because their "enforcement process[es] operate independently."[27]

---

26 Summary judgment motions on the Violation Letters remain pending in the *AstraZeneca* case. *See* No. 21-27, ECF Nos. 90-95.

27 HHS, Notice of Withdrawal of AO, at 1 (June 18, 2021), *available at* https://www.hhs.gov/guidance/document/notice-withdrawal-ao-contract-pharmacies-under-340b (last visited Nov. 4, 2021).

ii. The ADR Rule

1. Statutory Authority

Around the time HHS promulgated its 2010 Guidance on contract pharmacies, Congress enacted provisions in the Affordable Care Act ("ACA"), Pub. L. No. 111-148, 124 Stat. 119 (2010), to enhance compliance with the 340B Program. *Astra*, 563 U.S. at 115, 122 (stating that Congress amended § 340B "to strengthen and formalize [HHS'] enforcement authority" and to "provide for more rigorous enforcement"). Relevant here, Congress expressly instructed HHS to issue a regulation establishing a dispute resolution process for covered entities and manufacturers to adjudicate overcharges, duplicate discounting, and drug diversion. 42 U.S.C. § 256b(d)(3)(A). Prior to this legislation, no mandatory dispute resolution existed, but rather a voluntary one in which parties were "encouraged" to participate. 61 Fed. Reg. 65,406. To this end, the statute provides that:

> The Secretary shall promulgate regulations to establish and implement an administrative process for the resolution of claims by covered entities that they have been overcharged for drugs purchased under this section, and claims by manufacturers . . . of violations [of provisions prohibiting diversion of drugs and duplicate discounts], including appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through mechanisms and sanctions described [herein].

42 U.S.C. § 256b(d)(3)(A).

Among other things, the Secretary also "may establish such deadlines and procedures as may be necessary to ensure that claims shall be resolved fairly, efficiently, and expeditiously" and "by which a covered entity may discover and obtain such information and documents from manufacturers and third parties as may be relevant to demonstrate the merits of a claim." *Id.* §§ 256b(d)(3)(B)(ii)-(iii). Manufacturers must audit covered entities before initiating proceedings against them, *id.* § 256b(d)(3)(B)(iv), and any action taken in the ADR process "shall be a final

agency decision and shall be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction." *Id.* § 256b(d)(3)(C).

2. The Final ADR Rule

To meet its statutory obligations, HHS promulgated a final ADR Rule on December 14, 2020. 85 Fed. Reg. 80,632, 80,633 (Dec. 14, 2020). The Rule, in its current form, contains multiple provisions pertinent to this litigation. They are summarized below, with key parts bolded.

- The Rule creates "a decision-making body within the Department that, acting on an **express, written delegation of authority from the Secretary of HHS**, reviews and makes a **precedential and binding decision** for a claim brought under the ADR Process." 42 C.F.R. § 10.3.

- **The Secretary appoints at least six members to serve on the ADR Board**, consisting of individuals selected in equal numbers from HRSA, the Centers for Medicare and Medicaid Services, and HHS's Office of General Counsel, plus a non-voting member from the Office of Pharmacy Affairs. 85 Fed. Reg. 80,644.

- For each claim, the HRSA Administrator selects three members from the Board to serve on the ADR panel. **Panelists are replaced on individual panels by the HRSA Administrator for-cause only**, and are screened for "conflicts of interest." 85 Fed. Reg. 80,644. **I note, however, that the Rule contains no provisions as to removal from the Board itself. The Rule also contains no provisions as to the Secretary's power to reassign panelists**.

- ADR proceedings are **governed by the Federal Rules of Civil Procedure**. 42 C.F.R. § 10.23(b).

- ADR panels are granted discretion to "permit a covered entity limited discovery," "[r]eview and evaluate documents and other information" as needed, and "determine, in its own discretion, the most efficient and practical form of the ADR proceeding," including through conducting an evidentiary hearing **governed by the Federal Rules of Evidence**. 85 Fed. Reg. at 80,644-45; 42 C.F.R. §§ 10.20(c)(1), 10.22(a), 10.23(a).

- **Covered entities may bring "an action for monetary damages or equitable relief against a manufacturer**." 42 C.F.R. § 10.21(a)-(c); 85 Fed. Reg. at 80,635. CMPs may reach $5,000 per overcharge. *Id.* § 10.11(a). If a panel concludes that a party has failed to respond to an information request, it may enter judgment. 85 Fed. Reg. at 80,645.

- The Rule vests panels with "**jurisdiction to resolve all issues underlying any claim or defense**, including by way of example, those having to do with covered entity eligibility, patient eligibility, or manufacturer restrictions on 340B sales that the 340B ADR panel deems relevant for resolving an overcharge, diversion, or duplicate discount claim." *Id.* at 80,636.

- **A panel must "submit the final agency decision** to all parties and **to HRSA for appropriate action** regarding refunds, penalties, removal, or referral to appropriate Federal authorities." *Id.* at 80,646; 42 C.F.R. § 10.24(e).

- **A panel's decision is final**. 42 U.S.C. § 256b(d)(3)(C); 42 C.F.R. § 10.24(d). A dissatisfied party may seek **judicial review in an Article III court of competent jurisdiction**. 42 Fed. Reg. at 80,641; 42 C.F.R. § 10.23(d).

3. The Rulemaking Process

Congress originally instructed HHS to issue the ADR Rule by September 20, 2010, 180 days after it passed the ACA. Despite producing an Advance Notice of Proposed Rulemaking ("ANPRM") that year, HHS missed its deadline by over a decade. Indeed, HHS did not issue a Notice of Proposed Rulemaking ("NPRM") until 2016. 81 Fed. Reg. 53,381 (Aug. 12, 2016). The contents of the NPRM, specifically how it compares to the final Rule, is critical to the parties' dispute. The NPRM proposed to resolve claims through three-member panels "chosen from a roster of eligible individuals alternating from claim to claim, and one ex-officio, non-voting member chosen from the staff of [HHS's Office of Pharmacy Affairs]." *Id.* at 53,382. ADR panel members would be "Federal employees . . . with demonstrated expertise or familiarity with the 340B Program," as appointed by the Secretary. *Id.* Once assigned to a panel, the HRSA Administrator could reassign panelists "for cause," such as a dispute-specific conflicts of interest. *Id.* at 53,387. ADR panel decisions would "be binding upon the parties involved," as required by statute. *Id.* 53,385. And in all cases, panel decisions would "be submitted to [HRSA's Healthcare Systems Bureau] to take enforcement action or apply sanctions, as appropriate." *Id.*

During the 2016 notice and comment period, HHS received 31 comments. Sanofi recommended that HHS revise certain auditing guidelines. 85 Fed. Reg. 80,633 ("Commenters recommend that, before HRSA develops the ADR process, HRSA should . . . reform its guidelines regarding manufacturer audits of covered entities."). A prominent interest group, PhRMA, which has also sued HHS, proposed amending the 340B Program's definition of "patient," which appears to be defined by statute. Still other manufacturers raised concerns about panelist bias. In the end, HHS did not adopt any changes, and placed the NPRM as written on the Unified Agenda of Federal Regulatory and Deregulatory Actions ("Unified Agenda"), a semiannual compilation of regulations under agency development. In an abrupt about-face on August 1, 2017, HHS took down the NPRM from the United Agenda, which identified it as a "Completed Action," a designation given to "rulemakings that are being Withdrawn or ending their lifecycle with a regulatory action that completes the rulemaking."[28] Confusingly, however, HHS did not publish a notice of withdrawal in the Federal Register, a statutorily created periodical that Congress devised in part to notify interested parties of such actions. 44 U.S.C. § 1504 (designating the "Federal Register"); *id.* § 1505 (identifying documents to be published therein).

HHS did not take any further action until December 2020, when it published the final ADR Rule under a different Regulatory Identification Number ("RIN").[29] *Compare* 85 Fed. Reg. 80,632 (RIN 0906-AB26), *with* 81 Fed. Reg. 53,381 (RIN 0906-AA90). HHS did not explain in 2017 why it de-listed the NPRM from the United Agenda yet not from the Federal Register. HHS now explains, in the preamble to the final Rule, that it never "formally withdr[e]w" the NPRM,

---

28 HHS, About the Unified Agenda, *available at* https://bit.ly/2OYh3FZ (last visited Nov. 4, 2021).

29 A RIN is a number included in the headings of Rule and Proposed Rule documents in the Federal Register, the purpose of which is "to make it easier for the public and agency officials to track the publication history of regulatory actions throughout their development." HHS, FAQs, *available at* http://www.reginfo.gov/public/jsp/Utilities/faq.myjsp (last visited Nov. 4, 2021).

but merely paused it pursuant to a directive from the White House. 85 Fed. Reg. 80,633 (citing memo from President's Chief of Staff titled "Regulatory Freeze Pending Review"). In the Agency's view, this "left [the Rule] open as a viable option" in the future. *Id.* HHS, in turn, did not undertake a new notice and comment period in 2020, although it "considered [again] the comments received on the [2016] NPRM." *Id.* For instance, the Rule responds to manufacturers' concerns that panelists appointed by the Secretary may be biased, and should be replaced with neutral Administrative Law Judges, by stating that panelists "are uniquely situated to handle the complexities of the 340B Program and related disputes" and professional diversity among them ensures "relevant expertise and experience in drug pricing or drug distribution" and "in handling complex litigation." 85 Fed. Reg. at 80,634-35.

In a case in the Southern District of Indiana challenging the validity of the ADR Rule, a court found that Eli Lilly, the manufacturer suing the Government there, "demonstrated a fair likelihood . . . that the actions taken by [HHS] [ ] indicated to regulated entities that the NPRM on the ADR process had been withdrawn and no rulemaking was being considered, despite the fact that no notice of withdrawal was published in the Federal Register. Lacking an opportunity to engage in the comment process, Lilly's rights and interests [were] violated." *Eli Lilly & Co. v. Cochran*, No. 21-81, 2021 WL 981350, at *9 (S.D. Ind. Mar. 16, 2021). The court went on to enjoin HHS from implementing or enforcing the ADR Rule during the pendency of that case and as between those parties. *Id.* at *12.

iii. The Violation Letters

In August 2020, just before Plaintiffs announced their policies, HHS began "considering" whether to sanction various manufacturers for imposing restrictions on contract pharmacy arrangements. HHS warned manufacturers that they risked "undermin[ing] the entire 340B

Program and the Congressional intent behind [it]" and "restrict[ing] access" for "underserved and vulnerable populations" amidst a still-ongoing global pandemic.

HHS sent Plaintiffs individual Violation Letters on May 17, 2021, informing them that their policies "resulted in overcharges" in violation of § 340B.[30] The Letters stated that Plaintiffs' obligations "[are] not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs," and "[n]othing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory [duty] to offer 340B pricing on covered outpatient drugs purchased by covered entities." *Id.* After considering but rejecting various rationales, referencing the agency's past guidance documents, and evaluating an administrative record spanning 8,000 pages and consisting largely of complaints from covered entities, HHS instructed Plaintiffs to "immediately begin offering [their] covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements, regardless of whether they purchase through an in-house pharmacy," or face sanctions. *Id.* HHS recently referred Plaintiffs to the OIG. *See, e.g.*, No. 21-634, ECF No. 96. The Letters do not identify any specific complaints or overcharges as the basis for enforcement. Many of the complaints contain the generic message, "I am forced to pay WAC [wholesale acquisition costs] for [the drugs] for my contract pharmacies," while others include evidence such as spreadsheets, screenshots, order invoices, and affidavits attesting to lost savings from Plaintiffs' policies.

As with the AO and the ADR Rule, this Court is not the first to address the Violation Letters. The Southern District of Indiana recently issued a decision on a similar letter sent to Eli Lilly with respect to its contract pharmacy policy. *Eli Lilly v. United States Dep't of Health &*

30 *See, e.g.*, HRSA, Letter to Sanofi Regarding Sales to Covered Entities through Contract Pharmacy Arrangements (May 2020), *available at* https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hrsa-letter-sanofi-covered-entities.pdf (last visited Nov. 4, 2021).

Human Servs., et al., No. 21-81, 2021 WL 5039566 (Oct. 29, 2021). The court first upheld the letter as a valid exercise of HHS' statutory authority to permit covered entities to use contract pharmacies as a general dispensing mechanism. *Id.* at *20. The court also found no support for Eli Lilly's program imposing "extra-statutory conditions" on contract pharmacy use, *id.*, and rejected a challenge under the Takings Clause as an improper "vehicle for altering" the "harsh reality" that manufacturers may be forced to absorb the financial burdens of fraud or abuse within the 340B Program as it stands. *Id.* at *21 (quoting *Baker Cnty. Med. Servs., Inc. v. United States Atty. Gen.*, 764 F.3d 1274, 1280 (11th Cir. 2014)). However, the Indiana court faulted HHS for changing its position on "its authority to enforce statutory compliance" and vacated the letter for that reason.[31] *Id.* at *22, *25. The court expressly declined to decide whether covered entities may use unlimited contract pharmacies and stated that neither its decision nor the Eli Lilly letter depends on that premise, while urging Congress to pass new legislation to clarify the Program. *Id.* at *24.

F. The Present Litigation – Sanofi

Sanofi brought the instant suit on January 12, 2021, challenging all three agency actions described *supra*. Sanofi argues that the ADR Rule violates the Appointments Clause in Article II because panel decisions are "not subject to any further executive branch review" and panelists are "agency employees . . . protected by for-cause removal restrictions." San. Br., at 56-57. This is

31 The *Eli Lilly* Court also decided the legality of the AO even though it had been vacated by the *AstraZeneca* Court and withdrawn by HHS. The court reasoned that it is not "absolutely clear that the allegedly wrongful behavior could not reasonably be expected to recur" because HHS did not indicate "that the agency has fully and for all time (in the context of this case at least) abandoned the position laid out in" the AO. *Id.* at *12-14 (quoting *United States v. Concentrated Phosphate Export Ass'n*, 393 U.S. 199, 203 (1968)). I nevertheless decline to take up the AO, as I expect HHS will make substantial revisions to any future version, as a result of both *AstraZeneca* and *Eli Lilly*, assuming the agency issues one at all, which is far from certain. *See, e.g.*, *Ala. Power Co. v. EPA*, 40 F.3d 450, 456 (D.C. Cir. 1994) (declining to address additional claim because "decision to vacate the rule moots the issue"); *Nat'l Resources Def. Council v. EPA*, 489 F.3d 1250, 1262 (D.C. Cir. 2007) (dismissing as "moot" claim about vacated rule); *Fund for Animals, Inc. v. Hogan*, 428 F.3d 1059, 1064 (D.C. Cir. 2005) (holding challenge to environmental assessment and the regulations based upon it moot because they "are no longer in effect"). To find otherwise may be to engage in impermissible speculation.

particularly so, Sanofi contends, in light of *United States v. Arthrex*, 141 S. Ct. 1970 (2021), where the Supreme Court severed a statutory restriction preventing the Director of the Patent & Trademark Office ("PTO") from reviewing decisions rendered by Administrative Patent Judges ("APJs"). *Id.* at 1986-87. Sanofi also argues that the ADR Rule violates Article III because it adjudicates claims involving core private rights, which are usually reserved for the judiciary, and "empowers ADR panels to function like courts." San. Br., at 68.

Aside from these constitutional challenges, Sanofi argues that the ADR Rule violates the APA in at least three ways. First, HHS withdrew the NPRM in 2017, but did not initiate a new notice and comment period when it published the final Rule in 2020. Second, and relatedly, the final Rule is not a logical outgrowth of the NPRM because "[c]ritical provisions . . . [were] wholly absent [then]." *Id.* at 59. Specifically, panel decisions are now precedential, panels may award money damages or equitable relief, and ADR proceedings follow federal civil and evidentiary rules. Third, the Rule is arbitrary and capricious because HHS (i) did not respond to Sanofi's or PhRMA's comments during rulemaking; (ii) failed to adequately explain its reasons for choosing this particular ADR process; (iii) did not consider important aspects of the problem such as the "exponential" growth in contract pharmacy arrangements; (iv) lacks statutory authority to award money damages and equitable relief to covered entities; and (v) impermissibly expanded the scope of the ADR Rule to encompass "claims that a manufacturer has limited the covered entity's ability to purchase outpatient drugs at or below the 340B price," which Sanofi believes cannot constitute "overcharges" in the sense of § 340B. *Id.* at 77.

As to the Letter, Sanofi argues that the 340B statute does not permit HHS to require it to ship drugs to contract pharmacies at all, that it may impose conditions on "offers" to covered entities who use multiple contract pharmacy arrangements in any event, and that its Integrity

Initiative does not "overcharge" covered entities under § 340B because it imposes an access restriction not a higher price. Regardless, Sanofi contends, HHS' determination that it violated § 340B is arbitrary and capricious because the Letter (i) was not a product of reasoned decision-making; (ii) rests on the same premises, and repeats the same factual errors, as the AO; (iii) HHS adjudicated covered entities' complaints *ex parte*; (iv) HHS did not provide fair notice of the rule the Letter enforces; and (v) and the Letter did not go through notice and comment. San. Opp. Br., at 20-26.

Sanofi asks this Court to "set aside" HHS' actions, 5 U.S.C. § 706(2), by vacating the AO, the ADR Rule, and the Letter. *Council Tree Commc'ns, Inc. v. FCC*, 619 F.3d 235, 258 (3d Cir. 2010); *Sierra Club v. EPA*, 972 F.3d 290, 309 (3d Cir. 2020). In addition, Sanofi seeks declaratory relief to "lift the legal cloud over [its] Integrity Initiative." 28 U.S.C. § 2201(a); Fed. R. Civ. P. 57; *Christ the King Manor, Inc. v. HHS*, 730 F.3d 291, 321 (3d Cir. 2013) (remanding "with instructions to enter a declaratory judgment . . . that HHS's [action] was arbitrary and capricious under the APA"). HHS asks the Court to affirm the ADR Rule and the AO, and to permit its enforcement action in the Violation Letter proceed.

G. The Present Litigation – Novo

Novo sued on January 15, 2021, challenging the AO and the Violation Letter. Novo raises similar arguments as Sanofi, with the addition that, as to the Violation Letter, HHS' construction of the 340B statute—but apparently not the statute itself—would constitute an unconstitutional taking. Novo Br., at 3. Novo asks the Court to "strike down the government's December 30 decision and May 17 letter as unlawful and contrary to law," but "[a]t a minimum," recognize that "the December 30 decision and May 17 letter do not comply with the requirements of reasoned decision-making" and instruct HHS to "proceed through notice-and-comment rulemaking" if it

wishes to interpret the 340B Program as it proposes in the Letters. *Id.* at 4. At the same time, Novo submits that HHS' policies on "the use of contract pharmacies between 1996 and 2010 were lawful and consistent with the 340B statute." *Id.* at 11-12.

II. LEGAL STANDARDS

A. Summary Judgment

"[W]hen a party seeks review of agency action under the APA, the district judge sits as an appellate tribunal." *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001). In that posture, "[t]he entire case on review is a question of law," *Marshall Cnty. Health Care Auth. v. Shalala*, 988 F.2d 1221, 1226 (D.C. Cir. 1993), and the "usual summary judgment standard does not apply in the sense that the district court does not need to determine whether there are disputed facts to resolve at trial since the administrative agency is the finder of fact." *Neto v. Thompson*, No. 20-00618, 2020 WL 7310636, at * 3 (D.N.J. Dec. 10, 2020) (quotations and citation omitted); *Soccer Ctrs., LLC v. Zuchowski*, No. 17-1024, 2017 WL 4570290, at *5 (D.N.J. Oct. 13, 2017) (quotations and citation omitted); *Lacson v. U.S. Dep't of Homeland Sec.*, 726 F.3d 170, 171 (D.C. Cir. 2013) (noting in APA case that "determining the facts is generally the agency's responsibility, not ours"). Judicial review is also limited to the administrative record, since "[i]t is black-letter administrative law that in an [APA] case, a reviewing court should have before it neither more nor less information than did the agency when it made its decision." *CTS Corp. v. EPA*, 759 F.3d 52, 64 (D.C. Cir. 2014) (quotations omitted); *see also* 5 U.S.C. § 706 ("[T]he court shall review the whole record or those parts of it cited by a party."); *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 743 (1985) (noting that, when applying arbitrary and capricious standard under the APA, "[t]he focal point for judicial review should be the administrative record already in existence"); *Stringfellow Mem'l Hosp. v. Azar*, 317 F. Supp. 3d 168, 183 (D.D.C. 2018) (same).

B. The APA

The APA also provides the substantive standard of review. A reviewing court must "hold unlawful and set aside" any aspect of an agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A); "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," *id.* § 706(2)(C); or "without observance of procedure required by law." *Id.* § 706(2)(D); *see also Otis Elevator Co. v. Sec'y of Labor*, 762 F.3d 116, 120-21 (D.C. Cir. 2014). Section 706(2)(A) "is a catchall, picking up administrative misconduct not covered by the other more specific paragraphs." *Ass'n of Data Processing Serv. Orgs., Inc. v. Bd. of Governors of Fed. Reserve Sys.*, 745 F.2d 677, 683 (D.C. Cir. 1984) (Scalia, J.). While an agency "has discretion to design rules that can be broadly applied, sacrificing some measure of fit for administrability," *Leather Indus. of Am. v. EPA*, 40 F.3d 392, 403 (D.C. Cir. 1994) (quotations and citation omitted), an action is nonetheless arbitrary and capricious under § 706(2)(A) "if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicles Mfrs. Ass'n of United States, Inc. v. State Farm Mut. Automobile Ins. Co.*, 463 U.S. 29, 43 (1983); *Pharm. Research & Mfrs. of Am. v. FTC*, 790 F.3d 198, 209 (D.C. Cir. 2015).

The party challenging the agency action bears the "heavy burden" of proving that it is unlawful. *Van Hollen, Jr. v. FEC*, 811 F.3d 486, 495 (D.C. Cir. 2016). "Judicial review is . . . deferential, and a court may not substitute its own policy judgment for that of the agency. A court simply ensures that the agency has acted within a zone of reasonableness and, in particular, has reasonably considered the relevant issues and reasonably explained the decision." *Fed. Commc'ns*

Comm'n v. Prometheus Radio Project, 141 S. Ct. 1150, 1158 (2021). Review is "especially" deferential "with respect to matters relating to an agency's areas of technical expertise." *Fox v. Clinton*, 684 F.3d 67, 75 (D.C. Cir. 2012).

III. THE ADR RULE

A. Compliance with the APA

i. Whether the Final ADR Rules Satisfies Notice and Comment

I begin with the ADR Rule, which Sanofi insists should have gone through another round of notice and comment in 2020 before issuing. The APA's notice and comment requirements "serve the salutary purposes of '(1) ensuring that agency regulations are tested via exposure to diverse public comment, (2) ensuring fairness to affected parties, and (3) giving affected parties an opportunity to develop evidence in the record to support their objections to the rule and thereby enhance the quality of judicial review.'" *AFL-CIO v. Chao*, 496 F. Supp. 2d 76, 91 (D.D.C. 2007) (quoting *Int'l Union, United Mine Workers of Am. v. Mine Safety and Health Admin.*, 407 F.3d 1250, 1259 (D.C. Cir. 2005) (alterations omitted)). If an agency issues a binding pronouncement, like the ADR Rule, which the parties do not dispute as such, the agency "must observe the APA's legislative rulemaking procedures," chief among them, a notice and comment period. *General Electric Co. v. Envt'l Prot. Agency*, 290 F.3d 377, 382-83 (D.C. Cir. 2002); *U.S. Steel Corp. v. U.S. EPA*, 595 F.2d 207, 214 (5th Cir. 1979) (observing that the notice and comment requirement is "designed to ensure that affected parties have an opportunity to participate in and influence agency decision making at an early stage, when the agency is more likely to give real consideration to alternative ideas"); *Hoctor v. U.S. Dep't of Agric.*, 82 F.3d 165, 171 (7th Cir. 1996) (holding that purpose of notice and comment is to give interested parties the opportunity to "communicate their concerns in a comprehensive and systematic fashion").

Sanofi argues that HHS needed to initiate a new notice and comment period because it removed the NPRM from the Unified Agenda in 2017, which put Sanofi on notice that rulemaking was over and regulatory action was not forthcoming. According to Sanofi, this is particularly so in light of what it deems significant revisions to the final Rule compared to the original NPRM: panel decisions are *precedential*, not just binding, panels may award *money damages or equitable relief* to a covered entity in proceedings against a manufacturer, and federal procedural/evidentiary rules govern the ADR process. Also critical in Sanofi's view is that a 340B-focused trade publication reported the following statement from an HRSA official in response to an inquiry regarding the status of ADR rulemaking in March 2020: "HRSA does not plan to move forward on issuing a regulation due to the challenges with enforcement of guidance."[32] HHS responds that it never actually withdrew the NPRM in 2017 because it did not publish a notice in the Federal Register, and as such, it was proper to finalize the Rule in 2020 on the public's input from the initial comment period in 2016.

As an initial matter, the APA is silent with respect to how an agency must (or may) withdraw a proposed rule. Withdrawal is not expressly described in the statute. Of course, "[a]n agency is generally required by the APA to publish notice of *proposed* rulemaking in the Federal Register." *Mendoza v. Perez*, 754 F.3d 1002, 1020 (D.C. Cir. 2014) (emphasis added). But I have not found any authority requiring that an agency *withdraw* a rule in the same manner. Jane E. Carmody, *To Withdraw or Not to Withdraw: Reviewability of an Agency's Withdrawn Proposed Rule*, 93 WASH. L. R. 2107, 2110 (2018) (explaining why withdrawn proposed rules occupy a "unique area of administrative law").

32 Tom Mirga, *HRSA: 340B Dispute Resolution Will Stay on Hold Until We Get Broader Regulatory Authority*, 340B Report (Mar. 12, 2020), *available at* https://340breport.substack.com/p/your-340b-report-for-thursday-march-eae (last visited Nov. 4, 2021).

Although the APA does not outline specific procedures for the type of agency action at issue here, and there is little case law on it, the fundamental "object" of the statute remains "fair notice." *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 174 (2007). The relevant question is therefore whether, under the circumstances, HHS effectively communicated a withdrawal to interested parties, or whether they remained fairly apprised of potential action, which I determine in view of "the purposes of notice and comment." *Am. Water Works Ass'n v. EPA*, 40 F.3d 1266, 1274 (D.C. Cir. 1994) (stating that the purposes must be "adequately served") (quotations and citation omitted); *Dia Nav. Co. v. Pomeroy*, 34 F.3d 1255, 1265 (3d Cir. 1994) (stating that one such purpose is to "reintroduce public participation and fairness to affected parties after governmental authority has been delegated to unrepresentative agencies"); *Batterton v. Marshall*, 648 F.2d 694, 703 (D.C. Cir. 1980) ("Analysis that improves upon semantic play must focus on the underlying purposes of the procedural requirements at issue."). This is consistent with the approach other courts have taken to determine whether an agency has complied with the APA. *See, e.g.*, *Eli Lilly*, 2021 WL 981350, at *9 ("[T]he relevant inquiry is whether, through their actions and statements, Defendants effectively communicated a withdrawal of the proposed rule to the public."); *Cooling Water Intake Structure Coalition v. United States EPA*, 905 F.3d 49, 61 (2d Cir. 2018) ("A central question under the APA is whether the agency's notice would fairly apprise interested persons of the subjects and issues of the rulemaking."); *Yale New Haven Hosp. v. Azar*, 457 F. Supp. 3d 93, 104 (D. Conn. 2020) (same).

Given this case law, both parties overstate their positions in important ways. Sanofi, for instance, is incorrect that the mere passage of time between when a comment period ends and when a final rule issues is dispositive. Though the APA is silent on how much time is too much time, significant time can—and often will—pass. *See, e.g.*, *Food Labeling; Gluten-Free Labelling*

of Fermented or Hydrolyzed Foods, 85 Fed. Reg. 49,240 (Aug. 13, 2020) (five years); Anne Joseph O'Connell, *Agency Rulemaking and Political Transitions*, 105 N.W. L. REV. 471, 513-19 (2011) (analyzing 16,826 rulemakings between 1981 and 2009 and finding that they took, on average, 462.79 days, or 1.3 years, to complete; 8,737 "significant rulemakings" during the same time period, which took on average 596 days to complete, or nearly two years; and thousands of rulemakings "during which a presidential transition occurred after the NPRM," as here, which took on average 989.31 days, or nearly three years). On the other hand, HHS is incorrect to suggest that "the mere presence of a prior notice and comment record" automatically "render[s] the solicitation of new comments unnecessary." *Action on Smoking & Health v. C.A.B.*, 713 F.2d 795, 801 (D.C. Cir. 1983) [hereinafter *ASH*]. As the D.C. Circuit has held, although the APA does not set forth a time limit, "the useful life" of an NPRM "is not infinite." *Mobil Oil Corp. v. U.S. EPA*, 35 F.3d 579, 584 (D.C. Cir. 1994).

HHS is also incorrect that it did not terminate rulemaking simply because it did not publish notice in the Federal Register. HHS takes what some courts deem sufficient to effect withdrawal as synonymous with what the APA requires. *See, e.g.*, *Int'l Union, United Mine Workers of Am. v. U.S. Dep't of Labor*, 358 F.3d 40, 42 (D.C. Cir. 2004) (recognizing withdrawal of proposed rule published in the Federal Register); *Ctr. for Auto Safety v. Nat'l Highway Traffic Safety Admin.*, 710 F.2d 842, 844 (D.C. Cir. 1983) (same); *Cierco v. Lew*, 190 F. Supp. 3d 16, 21 (D.D.C. 2016) (same). HHS appears to acknowledge the limits of its own contention, stating that it "often accomplishe[d]" withdrawal "by a publication of . . . notice in the Federal Register," not that doing so is a hard-and-fast statutory requirement. U.S. Br., at 47. Indeed, while agencies customarily convey to the public that a rule is off the table through notice in the Federal Register, 78 Fed. Reg. 12,702 (Feb. 25, 2013); 79 Fed. Reg. 19,848 (Apr. 10, 2014); 83 Fed. Reg. 60,804 (Nov. 27, 2018);

84 Fed. Reg. 37,821 (Aug. 2, 2019), that best practice is just that—a practice rather than an affirmative command. I am not "free to impose upon agencies specific procedural requirements that have no basis in the APA." *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2385 (2020) (quotations and citation omitted). The APA sets forth the "maximum procedural requirements" an agency must follow to promulgate a rule, *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, Inc.*, 435 U.S. 519, 524 (1978), and provides "the full extent of judicial authority to review executive agency action for procedural correctness." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 513 (2009). At the same time, I reject Sanofi's position that HHS' decision to remove the NPRM from the Unified Agenda is sufficient, by itself, to erase the 2016 proposal. The Unified Agenda "does not create a legal obligation on agencies to adhere to schedules in this publication or to confine their regulatory activities to those regulations that appear within it," and merely represents what agencies "have tried to predict [as] their activities over the next 12 months." 86 Fed. Reg. 41,166, 41,167 (July 30, 2021). "Agencies may withdraw some of the regulations [ ] under development, and they may issue or propose other regulations not included in their agendas," which is why, for example, the Office of Information and Regulatory Affairs ("OIRA") has drawn a distinction between withdrawing a rule in the sense of the APA and de-listing it from the Unified Agenda.[33] *Id.*

Finally, I reject HHS' claim that it did not withdraw the NPRM simply because it calls its action (in hindsight) a pause in rulemaking. "Although [an] agency's characterization may provide some guidance in determining the nature of the challenged action, it is the substance of what the [agency] has purported to do and has done which is decisive." *Public Citizen v. Steed*, 733 F.2d

33 Dominic J. Mancini, OIRA, Guidance Implementing Executive Order 13771, Reducing Regulation and Controlling Regulatory Costs, at 4 (Apr. 5, 2017), *available at* https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2017/M-17-21-OMB.pdf (last visited Nov. 4, 2021).

93, 98 (D.C. Cir. 1984) ("An 'indefinite suspension' does not differ from a revocation simply because the agency chooses to label it a suspension."); *Natural Resources Defense Council v. U.S. EPA*, 683 F.2d 752, 763 n.23 (3d Cir. 1982) ("[A]n indefinite postponement which is never terminated is tantamount to a revocation. We must look at the character of the action taken at the time it is taken in order to determine whether the APA applies."). To summarize: the passage of time plus HHS' decision to remove the NPRM from the Unified Agenda is not dispositive of whether HHS needed to undertake new notice and comment, but neither is the existence of a prior comment period plus HHS' decision to keep the NPRM on the Federal Register and to deem it a mere pause.

Sanofi's challenge hinges on whether it *really* did not know about the final Rule's substance or when it would take effect, since "notice-and-comment processes that result in an unfair surprise being sprung on regulated entities are [of course] deficient." *Teva Pharms. USA, Inc. v. United States Food & Drug Admin.*, 514 F. Supp. 3d 66, 95 (D.D.C. 2020). Fair notice principles are in large part why the APA requires a "proposed rulemaking" to be "published in the Federal Register" and why an agency must inform the public of "the time, place, and nature of public rule making proceedings," "the legal authority under which the rule is proposed," and "the terms or substance of the proposed rule or a description of the subjects and issues involved." 5 U.S.C. § 553(b)(1)(3). Fair notice principles are also why "the decision to withdraw a proposed rule is subject to the same underlying requirement of 'reasoned decisionmaking' . . . that 'generally applies'" to initial rulemakings. *Env't Integrity Project v. McCarthy*, 139 F. Supp. 3d 25, 39 (D.D.C. 2015) (citations omitted). An agency may decide not to proceed with a proposed rule, *Neighborhood Assistance Corp. v. Consumer Fin. Prot. Bureau*, 907 F. Supp. 2d 112, 124 (D.C.C. 2012), but it may not withdraw a proposal for "no reason whatsoever," or without

adequately explaining its basis for doing so. *United Mine Workers*, 358 F.3d at 44 (quotations and citations omitted).

Given the above principles and facts, I do not find that HHS promulgated the final Rule out of the blue, that it truly constituted a "surprise edict" for Sanofi, or that HHS must start from scratch, although the four-year delay approaches the limit for taking action. Such a finding would overlook the important point that Congress mandated the ADR Rule through legislation, making it neither discretionary nor within HHS' power to decide whether to promulgate. The public and industry were well aware, in this regard, that HHS had to issue a final Rule at some point, sooner or later, to comply with Congress' directive. 42 U.S.C. § 256b(d)(3)(A). Sanofi thus could not have been reasonably caught off guard when the final Rule—on the horizon since 2010—issued. Because of the nature of the ADR Rule, there is also little reason to suspect harm to Sanofi, which might carry the day under different circumstances by requiring a greater degree of notice. *See, e.g.*, *Vill. of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 499 (1982) ("The degree of vagueness that the Constitution tolerates—as well as the relative importance of fair notice and fair enforcement—depends in part on the nature of the enactment."). The ADR Rule has a narrow subject matter, is civil not criminal, encompasses economic activity only, does not impose high compliance costs, does not upset Sanofi's settled business expectations or market operations, and Sanofi has long had to work with covered entities on an informal/voluntary basis to resolve pricing discrepancies, a relationship the Rule more or less formalizes.

Moreover, HHS expressed its intent to issue a final Rule in 2017 (around the time Sanofi claims it withdrew the NPRM) in another manufacturer-facing 340B regulation. 82 Fed. Reg. at 1,212 ("HHS is choosing to issue separate rulemakings for the different areas of the 340B Program . . . . HHS anticipates finalizing the [ADR] regulation after the comments have been reviewed and

considered."). And Sanofi has not pointed to *relevant* changes in the regulated market or 340B landscape in the interim that might make the prior notice and comment period stale, cause HHS to believe that there is no way of knowing whether the concerns underlying the original NPRM remain present today, or render the agency's information in 2016 particularly out of date now. *See, e.g.*, 76 Fed. Reg. 48,792-93 (Aug. 9, 2011) ("Although agencies should not automatically deem rulemaking comments to have become stale after any fixed period of time, [they] should closely monitor their rulemaking dockets, and, where an agency believes the circumstances surrounding the rulemaking have materially changed or the rulemaking record has otherwise become stale, consider the use of available mechanisms such as supplemental notices of proposed rulemaking to refresh the rulemaking record."); *compare Williams Natural Gas Co. v. FERC*, 872 F.2d 438, 449 (D.C. Cir. 1989) (rejecting government's contention that "staleness of the record" and a "long delay [in] itself" "justified [ ] termination of the rulemaking," even though government claimed that proposed rules were "no longer relevant to current conditions in the [regulated] market"), *with Ranchers Cattlemen Action Legal Fund v. U.S. Dep't of Agric.*, 566 F. Supp. 2d 995, 1007 (D.S.D. 2008) "[T]he USDA had acknowledged that it needed to consider new information from its investigations in order to ensure the appropriateness of the OTM beef provisions. The public needed to be notified of the USDA's findings and the impact of those findings, as well as given an opportunity to comment on the new information or to provide additional information. Thus, the Court cannot say that notice was adequate.").

As a final note, at the preliminary injunction stage, the Southern District of Indiana decided *Eli Lilly* differently, enjoining the ADR Rule as between those parties, pending a decision on the merits. The court emphasized the importance of fair notice, as I have done here. 2021 WL 981350, at *9. But I am unpersuaded by the court's characterization of HHS' actions. The court calls HHS

"duplicitous and misleading," *id.* at *10, whereas in my view, the agency may have been caught between transitioning administrations with dissimilar priorities. 82 Fed. Reg. at 8,346 (citing 2017 Presidential directive to pause all rulemaking pending review). The Indiana court also did not conduct its fair notice inquiry with an eye towards "the purposes of notice and comment," which again are "(1) to ensure that agency regulations are tested via exposure to diverse public comment, (2) to ensure fairness to affected parties, and (3) to give affected parties an opportunity to develop evidence in the record." *Am. Water Works*, 40 F.3d at 1274. Sanofi has known about the ADR Rule for over a decade, because Congress mandated it by statute—a critical fact the *Eli Lilly* Court omitted—and had a full opportunity to "test[]" or "develop" the Rule with comments in 2016, after which time nothing material *to the Rule* has changed. It is thus unclear how HHS did not comply with the "object" of the APA or "adequately serve[]" the goals of notice and comment, other than by delaying the Rule, which despite approaching the limit still does not suffice under these circumstances. Stated differently, "[t]he [APA] was adopted to provide . . . that administrative policies affecting individual rights and obligations be promulgated pursuant to certain stated procedures so as to avoid the inherently arbitrary nature of unpublished *ad hoc* determinations," a circumstance fundamentally different from the matter at hand. *Morton v. Ruiz*, 415 U.S. 199, 232 (1974) (emphasis in original).

In sum, agencies are not required to promulgate proposed rules immediately or within a certain timeframe, *Stringfellow*, 317 F. Supp. 3d at 185, but "are free—indeed, they are encouraged—to modify [them]." *Ne. Md. Waste Disposal Auth. v. EPA*, 358 F.3d 936, 951 (D.C. Cir. 2004). This entails a large measure of deference to the "timing and priorities of [an agency's] regulatory agenda," *WildEarth Guardians v. EPA*, 751 F.3d 649, 651 (D.C. Cir. 2014), and "the timetable of a rulemaking proceeding." *Sierra Club v. Gorsuch*, 715 F.2d 653, 658 (D.C. Cir.

1983); *Natural Resources Defense Council, Inc. v. SEC*, 606 F.2d 1031, 1056 (D.C. Cir. 1979) (holding that an agency "alone is cognizant of the many demands on it, its limited resources, and the most effective structuring and timing of proceedings to resolve those competing demands"); *National Congress of Hispanic American Citizens v. Usery*, 554 F.2d 1196, 1200 (D.C. Cir. 1977) (holding that an agency has "traditional agency discretion to alter priorities and defer action due to legitimate statutory considerations"); *Public Citizen v. Auchter*, 702 F.2d 1150, 1158 (D.C. Cir. 1983) ("[D]elays that might be altogether reasonable in the sphere of economic regulation are less tolerable when human lives are at stake."). In addition, "[a]gencies obviously have broad discretion to reconsider a regulation at any time." *Clean Air Council v. Pruitt*, 862 F.3d 1, 8 (D.C. Cir. 2017). Because the ADR Rule was always an inevitability, and never merely an option, HHS did not need to go through a second notice and comment period to issue the final Rule in 2020.[34]

ii. Whether the Final ADR Rule Satisfies the Logical Outgrowth Doctrine

I also reject Sanofi's "related suggestion" that HHS needed to undertake a new notice and comment period in 2020 because the final Rule is not a logical outgrowth of the NPRM. *Abington Mem'l Hosp. v. Burwell*, 216 F. Supp. 3d 110, 134 (D.D.C. 2016) (observing that logical outgrowth is relevant to both the question whether there is fair notice and the question whether there is "a meaningful opportunity to comment" on the substance of a final rule "even if" an NPRM "provided fair notice" that one would issue). Under the APA, an agency engaging in notice and comment rulemaking must publish an NPRM that includes "either the terms or substance of the proposed

34 Under 5 U.S.C. § 553(b)(B), an agency may forego notice and comment when it "for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." *Id.* HHS did not invoke good cause in the final Rule, and it has already provided a comment period to interested parties, making this exception inapplicable.

rule or a description of the subjects and issues involved." 5 U.S.C. § 553(b)(3). Courts interpret this to mean that "the final rule the agency adopts must be 'a logical outgrowth of the rule proposed.'" *Long Island Care*, 551 U.S. at 174. Fair notice is a bedrock of the logical outgrowth doctrine, as it is with the comment requirement. *Owner-Operator Indep. Drivers Ass'n, Inc. v. Fed. Motor Carrier Safety Admin.*, 494 F.3d 188, 209 (D.C. Cir. 2007) ("As the Supreme Court recently explained, the object of the logical outgrowth test 'is one of fair notice.'"); *Stringfellow*, 317 F. Supp. 3d at 185 (rejecting argument that rulemaking was not a logical outgrowth, and in turn, that it violated fair notice or required new comment).

A final rule is a "logical outgrowth" of a proposed rule if regulated parties "'should have anticipated' that the change was possible, and thus reasonably should have filed their comments on the subject during the notice-and-comment period." *Northeast Md. Waste Disposal Auth. v. EPA*, 358 F.3d 936, 952 (D.C. Cir. 2004); *City of Waukesha v. EPA*, 320 F.3d 228, 245 (D.C. Cir. 2003). A final rule is not a logical outgrowth if regulated parties would have had to "divine [the Agency's] unspoken thoughts," *Ariz. Pub. Serv. Co. v. EPA*, 211 F.3d 1280, 1299 (D.C. Cir. 2000) (quotations and citation omitted), or where the rule is "surprisingly distant" from what the agency first proposed. *United Mine Workers*, 407 F.3d at 1259-60. Sanofi argues that supplemental notice and comment is necessary for HHS to promulgate the final ADR Rule given the significance of certain provisions which did not appear in the NPRM: panel decisions are precedential, panels may award money damages or equitable relief to a covered entity in a proceeding against a manufacturer, and proceedings are governed by the Federal Rules of Civil Procedure and Evidence.

1. Money Damages and Equitable Relief

I start with Sanofi's claim that the NPRM did not raise the possibility of money damages or equitable relief. The NPRM permits "[c]laims by covered entities that they have been overcharged by manufacturers for drugs purchased under this section." 81 Fed. Reg. at 53,383. The final ADR Rule is more specific as to the relief available: "[a]ny covered entity or manufacturer may initiate an action for monetary damages or equitable relief against a manufacturer or covered entity." 85 Fed. Reg. at 80,635; 42 C.F.R. § 10.21(a). Contrary to Sanofi's contention, given the regulatory language, these iterations of the Rule are "materially identical." *Post Acute Med. At Hammond, LLC v. Azar*, 311 F. Supp. 3d 176, 185 (D.D.C. 2018). Sanofi could not have understood "overcharge claims" in the proposed rule to entail any more or less than what the final Rule details: a request for a refund/credit (money damages) or for an order to cease certain pricing activity (equitable relief). Without such forms of relief, Congress' statutory scheme would be largely ineffective. *Astra*, 563 U.S. at 121-22 (stating that Congress amended § 340B "to strengthen and formalize [HHS'] enforcement authority"); *id.* at 121 ("[I]n the []ACA, Congress directed HHS to create a formal dispute resolution procedure, institute refund and civil penalty systems, and audit manufacturers."); *id.* at 115 ("If a manufacturer overcharges a covered entity, HRSA may require the manufacturer to reimburse the covered entity; HRSA may also terminate a manufacturer's PPA."). Certainly, based on the plain meaning of the Rule, Sanofi did not need to "divine" HHS' "unspoken thoughts" to make the inference that money damages and equitable relief are predictable in the context of an alleged overcharge. Such remedies are "in character with the original scheme." *South Terminal Corp. v. EPA*, 504 F.2d 646, 658 (1st Cir. 1974); *Natural Res. Def. Council, Inc. v. U.S. EPA*, 824 F.2d 1258, 1283 (1st Cir. 1987) (justifying even "substantial changes from the proposed version") (quotations and citations omitted). Or, put differently, "Plaintiffs cannot reasonably contend that they lacked fair notice that [these remedies]

would apply just because, in the nearly identical [2020] Final Rule, the Secretary decided to give a further example of what [a claim for an overcharge] would mean." *Abington Mem'l Hosp.*, 216 F. Supp. 3d at 135.

2. Federal Rules of Civil Procedure and Evidence

The NPRM further states that the ADR process "is not intended to be a trial-like proceeding governed by formal review of evidence and procedure." 81 Fed. Reg. at 53,382. Yet, in the final ADR Rule, HHS gives ADR panels "discretion in admitting evidence and testimony during the course of a proceeding," and "the Federal Rules of Civil Procedure . . . and the Federal Rules of Evidence . . . to the extent applicable, shall apply," unless the parties agree otherwise. 85 Fed. Reg. at 80,641. While the final Rule constitutes a reversal of HHS' initial position in this regard, HHS changed course only "after further consideration" of comments it received during the rulemaking process, and in an effort "to provide [ ] guidance" to regulated entities who raised concerns. 85 Fed. Reg. at 80,641 (proposing that ADR panels should hear live evidence/testimony); *id.* (asking HHS to "establish safeguards and protections" during the ADR process); *id.* at 80,633 ("Several commenters urge HRSA to adopt those conventions for ascertaining deadlines that are commonly used by other administrative bodies and courts . . . . HHS agrees with these comments."). HHS' decision thus "indicates that the agency treats the notice-and-comment process seriously." *Am. Med. Ass'n v. United States*, 887 F.2d 760, 767 (7th Cir. 1989).

By all accounts, indeed, HHS' actions showed a "willing[ness] to modify its position where the public's reaction persuades [it] that its initial regulatory suggestions were flawed." *Am. Med. Ass'n*, 887 F.2d at 767; *Pennzoil Co. v. FERC*, 645 F.2d 360, 372 (5th Cir. 1981) (holding that agency's reversal "demonstrates not that the agency acted arbitrarily, but simply that the administrative process was working . . . . modification of proposed rules in light of written and

oral presentations is the heart of the rulemaking process"). As the D.C. Circuit has reiterated, "[a] contrary rule would lead to the absurdity that in rulemaking under the APA the agency can learn from the comments on its proposals only at the peril of starting a new procedural round of commentary." *Int'l Harvester Co. v. Ruckelshaus*, 478 F.2d 615, 632 & n.51 (D.C. Cir. 1973); *Trans-Pacific Freight Conference v. Federal Maritime Comm'n*, 650 F.2d 1235, 1249 (D.C. Cir. 1980) (stressing that the APA should not be construed to place administrative agencies in the dilemma of either ignoring comments, in which case a final rule may be invalidated due to the agency's intransigence, or modifying its proposals, thereby triggering another notice and comment period). Sanofi's position would turn "the comment period [into] a perpetual exercise rather than a genuine interchange resulting in improved rules," *Connecticut Light & Power Co. v. Nuclear Regul. Comm'n*, 673 F.2d 525, 533 (D.C. Cir. 1982), and pay short shrift to "the public interest in expedition and finality," *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 547 (D.C. Cir. 1983), which counterbalances the values served by the APA's notice and comment requirement.

3. Precedential Decisions

Sanofi also claims that the NPRM did not raise the possibility that ADR panel decisions could be precedential. It is true that the NPRM provides that decisions will be "binding," 81 Fed. Reg. at 53,385, while the final Rule provides that decisions "shall be" both binding and "precedential." 85 Fed. Reg. at 80,635, 80,641. But that difference is not dispositive, because HHS received numerous comments on the legal effect of panel decisions during the notice period. *See, e.g.*, 85 Fed. Reg. at 80,641 ("*Comment*: . . . . HHS publish all findings and decisions by the 340B ADR Panel to enable all parties to be informed and more compliant. These commenters suggest that publication of the ADR's decisions will also prevent inconsistent decisions and unsupported

rulings. *Response*: HHS agrees."); *id.* at 801,642 ("*Comment*: . . . . Once the 340B ADR Panel reaches its decision, HHS should mandate the issuance of a summary that includes a transparent analysis of the reasons for the decision, without disclosing any proprietary or otherwise confidential information. HHS should also recognize that the 340B ADR Panel decision is binding on the parties involved in the dispute (unless otherwise overturned by a court acting pursuant to the [APA]), but is not binding on third parties. *Response:* HHS agrees."); *id.* ("*Comment*: Commenters express concern that HRSA should not use its enforcement authority to transform a 340B ADR Panel decision into a broad 340B policy decision. The commenters explain that enforcement should be limited to the parties to the ADR proceeding. 340B ADR Panel decisions should not have general applicability. *Response*: As set forth in section 10.23(b)(2), 340B ADR Panel decisions will be final agency decisions, binding on the parties, and precedential."). Whether final decisions should be precedential appears to be one of the more contested issues discussed during the notice period, suggesting that interested parties widely anticipated the approach HHS ultimately adopted and that Sanofi (like many others who did so) had a reasonable chance to provide input on this issue. *Am. Water Works*, 40 F.3d at 1274 ("We apply [the logical outgrowth] standard functionally by asking . . . whether a new round of notice and comment would provide *the first opportunity* for interested parties to offer comments that could persuade the agency to modify its rule.") (emphasis added).

Of course, an agency "cannot bootstrap notice from a comment." *Fertilizer Inst. v. EPA*, 935 F.2d 1303, 1312 (D.C. Cir. 1991). "[N]otice necessarily must come—if at all—from the [a]gency." *Small Refiner*, 705 F.2d at 549. And a regulated entity such as Sanofi is not expected to monitor every single public submission. *Am. Fed'n of Labor v. Donovan*, 757 F.2d 330, 340 (D.C. Cir. 1985) (holding that the court cannot "properly attribute notice to [interested parties] on

the basis of an assumption that they would have monitored the submission of comments"). Still, comments on an agency proposal can be relevant if they raise a foreseeable possibility of agency action. *NRDC v. Thomas*, 838 F.2d 1224, 1243 (D.C. Cir. 1988); *Mid Continent Nail Corp. v. United States*, 846 F.3d 1364, 1378 (Fed. Cir. 2017) ("[R]esponses by commentators may be relevant to the court's inquiry under the logical outgrowth doctrine."); *United Mine Workers*, 407 F.3d at 1261 (stating that this is simply "the outer limits of the 'logical outgrowth' doctrine"). Given the volume of on-point public commentary about whether panel decisions should have some precedential effect, the notice and comment period here involved "a wide range of interested parties who read the proposed rule, saw the possibility of [precedential decisions], and wrote to the agency requesting [or debating] them." *Neighborhood Assistance Corp. of Am. v. Consumer Fin. Prot. Bureau*, 907 F. Supp. 2d 112, 125 (D.D.C. 2012). Likewise, in much the same way as above, HHS' back-and-forth with interested parties—which the APA not only envisions but commands—demonstrates that HHS engaged in the necessary statutory process. *Envtl. Integrity Project v. EPA*, 425 F.3d 992, 996 (D.C. Cir. 2005) (rejecting logical outgrowth only where "final rule that finds *no roots* in the agency's proposal") (quotations and citations omitted) (emphasis added); *Conn. Light & Power*, 673 F.2d at 533 (accepting a modification as a logical outgrowth if NPRM merely "adequately framed the subjects for discussion").

In sum, the final ADR Rule is a logical outgrowth of the NPRM, which "need not specify every precise proposal which [HHS] may ultimately adopt," but must be "sufficient to fairly apprise interested parties of the issues involved." *Nuvio Corp. v. FCC*, 473 F.3d 302, 310 (D.C. Cir. 2006) (quoting *Action for Children's Television v. FCC*, 564 F.2d 458, 470 (D.C. Cir. 1977)); *Horsehead Res. Dev. Co. v. Browner*, 16 F.3d 1246, 1268 (D.C. Cir. 1994) (holding that logical

outgrowth doctrine "does not require the agency to assiduously lay out every detail of a proposed rule for comment").

iii. Whether the Final ADR Rule is Arbitrary and Capricious

Finally, Sanofi contends that the ADR Rule is arbitrary and capricious because HHS (i) did not respond to certain comments during rulemaking; (ii) failed to explain its reasons for choosing this particular ADR design; (iii) did not consider important aspects of the problem such as "exponential" growth in contract pharmacy arrangements; (iv) lacks statutory authority to award money damages and equitable relief to covered entities; and (v) expanded the scope of the ADR Rule to encompass "claims that a manufacturer has limited the covered entity's ability to purchase outpatient drugs at or below the 340B price" in violation of the authorizing statute. I address each in turn.

1. Response to Comments

Sanofi first claims that HHS did not respond to its comment suggesting revisions to HRSA's auditing guidelines. 85 Fed. Reg. at 80,633 ("Commenters recommend that, before HRSA develop the ADR process, HRSA should . . . reform its guidelines regarding manufacturer audits of covered entities."). Sanofi deems this important because, by law, a manufacturer must audit a covered entity "as a prerequisite to initiating" an ADR petition. 42 U.S.C. § 256b(d)(3)(B)(iv). Under the APA, an agency "need not address every comment" it receives, *Louisiana Forestry Ass'n Inc. v. Sec'y U.S. Dep't of Lab.*, 745 F.3d 653, 679 (3d Cir. 2014) (citing *City of Waukesha v. EPA*, 320 F.3d 228, 257 (D.C. Cir. 2003)), but only "relevant and significant" ones. *Nazareth Hosp. v. Sec'y U.S. Dep't of Health & Hum. Servs.*, 747 F.3d 172, 185 (3d Cir. 2014) (quoting *Pub. Citizen, Inc. v. FAA*. 988 F.2d 186, 197 (D.C. Cir. 1993)). Significant comments are those "which, if true, raise points relevant to the agency's decision and which, if adopted, would require

a change in an agency's proposed rule." *Home Box Office, Inc. v. FCC*, 567 F.2d 9, 35 n.58 (D.C. Cir. 1977). The APA is "not particularly demanding" in this respect. *Pub. Citizen*, 988 F.2d at 197.

I disagree with Sanofi's position in light of this case law. To start, it is dispositive that HHS *did* respond to Sanofi's comment. 85 Fed. Reg. at 80,633 ("Neither updated manufacturer audit guidelines nor the finalization of the 340B mega-guidance is needed to finalize the ADR process."). Sanofi simply disagrees with how HHS did so. But that does not rise to the level of a violation under the APA. In any event, although the ADR Rule requires manufacturers to audit covered entities before filing disputes against them, the auditing guidelines are well-defined in a different agency rule, as referenced in HHS' response. 80 Fed. Reg. 52,300, 52,315, 52,322-23 (Oct. 27, 2015).[35] Thus Sanofi did not actually propose a change to the ADR Rule itself, or raise "significant problems" with it. *Covad Commc'ns Co. v. FCC*, 450 F.3d 528, 550 (D.C. Cir. 2006) (collecting cases). Instead, Sanofi suggested that HHS either forestall rulemaking to address a different issue, add Sanofi's issue to the scope of its proposed Rule, or revise/finalize 80 Fed. Reg. 52,300 first. But the APA does not entitle Sanofi to any such course of action. *See, e.g.*, *Sec. Indus. & Fin. Mkts. Ass'n v. U.S. Commodity Futures Trading Comm'n*, 67 F. Supp. 3d 373, 429 (D.D.C. 2014) (stating that comments cannot "unilaterally expand the scope of [a proposed rule]," nor compel an agency "to initiate a separate rulemaking to address" another problem); *Nat'l Mining Ass'n v. Mine Safety and Health Admin.*, 116 F.3d 520, 549 (D.C. Cir. 1997) (holding that substantive response to comment not required where comments are "beyond the scope of the rulemaking"). Contrary to Sanofi's position, "[a]n agency enjoys broad discretion in determining how best to handle related, yet discrete, issues in terms of procedures, and priorities . . . [and] need not solve every problem before it in the same proceeding." *Mobil Oil*, 498 U.S. at 230 (citations

35 The 340B Drug Pricing Program Omnibus Guidance.

omitted). Sanofi's claim that HHS did not adequately respond to PhRMA's comment suggesting revisions to § 340B's definition of "patient" likewise suffers from the same flaws. *See, e.g.*, 85 Fed. Reg. at 80,638 ("HHS is clarifying . . . that a 340B ADR Panel's review . . . may include . . . whether an individual does not qualify as a patient for 340B Program purposes.").

2. Reasons for This Particular ADR Process

Sanofi next asserts that "HHS failed to reasonably explain its reasons for choosing the design of the ADR process." Am. Compl., ¶ 113. However, Sanofi does not submit any supporting evidence in its briefs or make any substantive arguments to this end, and has accordingly abandoned this claim. *Yucis v. Sears Outlet Stores, LLC*, No. 18-15842, 2019 WL 2511536, at *4 & n.4 (D.N.J. June 18, 2019); *Allen v. Quicken Loans Inc.*, No. 17-12352, 2018 WL 5874088, at *10 (D.N.J. Nov. 9, 2018) (granting motion to dismiss and stating that "[plaintiff] does not respond to this argument, and in fact, his brief appears to abandon the claim entirely by not mentioning it at all"); *Iwanicki v. Bay State Mill. Co.*, No. 11-1792, 2012 WL 4442643, at *5 (D.N.J. Sept. 21, 2012) (granting motion to dismiss when the plaintiff did "not respond to the arguments" in defendant's moving brief or offer additional support for plaintiff's position); *Michel v. New Jersey*, No. 10-3892, 2011 WL 1584287, at *3 (D.N.J. Apr. 25, 2011) (deeming claims abandoned and dismissing them because the plaintiff did not offer any opposition to defendants' motion to dismiss on several claims).

3. Important Aspects of the Problem

Sanofi also claims that HHS failed to account for three important considerations when it promulgated the final ADR Rule: "the exponential increase in the use of contract pharmacies, the growing evidence of abuses in the 340B Program documented by the government itself, and the various responses of manufacturers, including the Integrity Initiative." San. Br., at 79. There is no

bright-line test for deciding whether an agency has sufficiently considered an issue in the sense of the APA, but in general, it must weigh relevant alternatives and balance reliance interests. *See, e.g.*, *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1913 (2020). "Reversal is appropriate only where the administrative action is irrational or not based on relevant factors." *NVE, Inc. v. Dep't of Health & Human Servs.*, 436 F.3d 182, 190 (3d Cir. 2006).

Sanofi's assertions in this context carry no weight. First, the ADR Rule *does* address abuses in the 340B Program by expressly permitting manufacturers to initiate proceedings against covered entities for "diversion or duplicate discounts." 85 Fed. Reg. at 80,633 ("The purpose of the ADR process is to resolve . . . (2) claims by manufacturers, after a manufacturer has conducted an audit as authorized by section 340B(a)(5)(C) of the PHSA, that a covered entity has violated the prohibition on diversion or duplicate discounts."). Second, HHS limited the ADR Rule to these types of claims, plus overcharges, because Congress specifically instructed HHS to do so through legislation. 42 U.S.C. § 256b(d)(3)(A); 85 Fed. Reg. at 80,633 ("340B(d)(3) [of] the PHSA[] [ ] requires the Secretary to promulgate regulations establishing and implementing a binding ADR process for certain [statutorily defined] disputes arising under the 340B Program."). HHS could not have included or adjudicated other disputes without exceeding its lawful authority.

Third, even if HHS could lawfully address other types of claims, the ADR Rule merely defines the procedures for resolving disputes, and Sanofi does not argue how specifically its Integrity Initiative or the growth in contract pharmacy arrangements entail problems that relate to the logistics of dispute resolution. *Pharm. Research*, 43 F. Supp. 3d at 42 ("Here, Congress has given HHS rulemaking power *specifically for purposes of administering a dispute resolution process* . . . . Congress has specifically delineated the scope of HHS's rulemaking authority in that regard.") (internal citation omitted). In short, Sanofi has failed to show that the problems it raises

with respect to the 340B Program themselves impact the *processes* set out in the ADR Rule. And, more importantly, "HHS has not been granted broad rulemaking authority to carry out all the provisions of [§] 340B." *Id.*

4. Statutory Authority for Money Damages and Equitable Relief

Next, Sanofi challenges whether ADR panels have Congressional authority to award money damages or equitable relief. Under 42 U.S.C. § 256b(d)(3)(A), the Secretary must establish "appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through the mechanisms and sanctions described [under paragraphs (1)(B) and (2)(B)]." *Id.* The Secretary may delegate this authority to the ADR Board. *See, e.g.*, 42 C.F.R. § 10.3 (stating that the ADR Rule creates "a decision-making body within the Department [ ] acting on an express, written delegation of authority from the Secretary of HHS"). In Sanofi's view, the "mechanisms and sanctions" enumerated in the statute do not include money damages and equitable relief as the ADR Rule defines them.

At the outset, according to the terms of the ADR Rule, a panel cannot impose a remedy at all, a premise on which Sanofi's challenge depends. A panel must instead "submit the final [ ] decision . . . *to HRSA for appropriate action regarding refunds, penalties, removal, or referral to appropriate Federal authorities*." 85 Fed. Reg. at 80,646 (emphasis added); 42 C.F.R. § 10.24(e). Neither does it appear that the process ends there. Should HHS agree with the panel's decision and wish to pursue a refund or a CMP, it must send the decision to the OIG, a referral which entails its own procedural safeguards. *See, e.g.*, 82 Fed. Reg. at 1,230; 42 C.F.R. § 10.11(a); 42 C.F.R. § 1003.[36] Chief among these: Sanofi would be entitled to a hearing before an ALJ with counsel,

36 42 C.F.R. § 1003.100(b)(2) sets forth "appeal rights of any person subject to a [CMP]." HHS has stated that CMPs arising out of § 340B "will be imposed pursuant to the applicable procedures contained in [§] 1003," and "[n]o further rulemaking is required to apply the procedures at [that section of the federal code] to [agency-imposed sanctions under the 340B Program]." 82 Fed. Reg. at 1,227.

discovery, oral argument, witness testimony, documentary evidence, cross-examination, and post-hearing findings of fact/conclusions of law. 42 U.S.C. § 1005.2-3 (applying to any sanctions imposed pursuant to § 1003.100(b)(2)). This makes clear that an ADR panel does not have the power to award relief other than to issue a judgment, which must always be effectuated (or not) by HHS. Or, as the agency states, "the 340B ADR Panel may make recommendations to HRSA for sanctions, including referrals to the HHS Office of Inspector General for its consideration of civil monetary penalties, as appropriate. Whether sanctions or remedial action is appropriate will be dependent on the type of violation that occurred . . . . HHS believes that the form of enforcement should be left open to permit HHS maximum flexibility in determining what is appropriate given the specific facts of each situation." 85 Fed. Reg. 80,642. Sanofi nevertheless argues that ADR panels adjudicate not just questions of compliance but "*actions* for monetary damages or equitable relief." San. Br., at 70 (quoting 42 C.F.R. § 10.21(a)) (emphasis in brief). Yet, the language on which Sanofi relies comes from a provision governing how covered entities or manufacturers "initiate[] an action," not what relief an ADR panel can provide, and read in context, the word "action" simply means "claim" or "petition."

Setting that aside, the ADR Rule permits money damages in the classic legal sense: compensatory payments for losses sustained as a result of overcharges (by a manufacturer) or drug diversion/duplicate discounting (by a covered entity). *See, e.g.*, *Pernell v. Southall Realty*, 416 U.S. 363, 370 (1974) ("'[W]here an action is simply for the recovery . . . of a money judgment, the action is one at law.'") (quoting *Whitehead v. Shattuck*, 138 U.S. 146, 151 (1891)). This finds ample support in the authorizing statute. *See, e.g.*, 42 U.S.C. § 256b(d)(1)(B)(ii) (requiring manufacturers to "issue refunds . . . in the event that there is an overcharge"); *id.* § 256(d)(1)(B)(vi) (imposing "sanctions in the form of [CMPs]" on manufacturers for overcharges); *id.* §

256(d)(1)(B)(v) (permitting "[s]elective auditing of manufacturers and wholesalers to ensure the integrity of the drug discount program," which may entail liability to covered entities for overpriced drugs); *id.* § 256(d)(2)(B)(v)(I) (imposing "a monetary penalty" on covered entities, which they "pay . . . to a manufacturer," for program misuse); *id.* § 256b(a)(5)(D) (requiring covered entities to pay manufacturers "an amount equal to the reduction in price of the drug" if an audit finds a 340B violation); *Astra*, 527 U.S. at 113 (stating that Congress directed HHS to "institute refund and civil penalty systems" and to "perform audits of manufacturers" to that end).

The same is true for equitable relief. The ADR Rule uses that term to encompass the various non-monetary enforcement actions specified by statute and integral to program compliance, *AMG Cap. Mgmt., LLC v. Fed. Trade Comm'n*, 141 S. Ct. 1341, 1348 (2021) ("The language and structure of § 13(b), taken as a whole, indicate that the words 'permanent injunction' have a limited purpose."), as well as to refer to a decision concluding that a covered entity or manufacturer has violated § 340B, akin to a declaratory judgment or cease and desist order. *See, e.g.*, 42 U.S.C. § 1396r-8(b)(4)(B) (permitting HHS to terminate a PPA with a manufacturer who violates § 340B and remove it from the Program); *id.* § 256b(d)(1)(B)(i)(IV) (requiring "manufacturers to take [ ] corrective action as is appropriate in response to [any] price discrepancies"); *id.* § 256b(d)(B)(II) (empowering the Secretary to "remov[e] [a] covered entity from the drug discount program"); *id.* § 256b(d)(B)(III) (empowering the Secretary to "refer[] matters to appropriate Federal authorities . . . for consideration of appropriate action under other Federal statutes"). Ultimately, I find that Sanofi's argument mischaracterizes the ADR Rule as permitting panels to grant equitable remedies without limitation when in actuality the Rule does not sweep that far.

5. Statutory Authority to Adjudicate Certain Types of Overcharges

Finally, Sanofi contends that the 340B statute authorizes HHS to adjudicate only a certain type of overcharge in ADR proceedings: when a manufacturer misprices a 340B drug, but not when one denies a covered entity access to the 340B Program altogether or restricts Program participation. San. Br., at 78 ("[A] claim alleging that a drug manufacturer 'has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price' differs from an 'overcharge[]' claim because it challenges a manufacturer's practices rather than its prices."). To the extent that the ADR process encompasses practices, Sanofi argues, it goes too far.

I cannot agree here either. HHS has consistently defined overcharge to cover precisely the conduct at issue in Sanofi's Integrity Initiative. In 2010, the agency wrote in its ANPRM that it "may consider claims of overcharge to include direct and indirect evidence of a violation, such as cases where refusal to sell at the 340B price has led to the purchase of the covered outpatient drug outside of the 340B Program." 75 Fed. Reg. 57,233, 57,234 (Sept. 20, 2010). HHS then echoed this interpretation in its 2015 CMP rule, emphasizing "the need to approach each instance of an overcharge with a full view of the surrounding circumstances," stating that a manufacturer overcharges a covered entity when there is a "documented refusal to sell or make drugs available at the 340B price" which "resulted in the covered entity purchasing at the non-340B price," and rejecting/rolling back attempts to specifically enumerate what situations should be exempt from the "knowing and intentional overcharge" standard.[37] 82 Fed. Reg. at 1,221-23, 1,226 ("HHS has decided . . . to allow OIG the necessary flexibility to evaluate each instance of overcharge on a case by case basis."). Likewise, in 42 C.F.R. § 10.21(c)(1), HHS defines an overcharge to encompass allegations "that a manufacturer has limited the covered entity's *ability* to purchase

37 Consistently, 82 Fed. Reg. 1,210 states that a manufacturer does *not* overcharge a covered entity when the "covered entity chooses to order non-340B priced drugs and the order is not due to a manufacturer's refusal to sell or make drugs available at the 340B price." *Id.* at 1,221.

outpatient drugs." *Id.* (emphasis added). To the extent that HHS sees no meaningful statutory distinction between a covered entity's claim that a manufacturer mispriced a 340B drug and its claim that it could not buy the drug at the discounted rate at all, I find its construction to be correct. *See infra*. And, of course, it is implausible that Congress would require the Secretary to establish a process to adjudicate overcharges for covered drugs, yet not intend that process to include claims that a covered entity was denied the ability to make a purchase in the first place, a "practice" that inherently implicates "prices." The ADR Rule accordingly complies with the APA.

B. Compliance with the Appointments Clause in Article II

Turning to the constitutional claims, Sanofi argues that ADR Board members are principal officers whose appointments violate Article II. This must be so, Sanofi maintains, because panelists "make final precedential determinations on behalf of HHS that are not subject to any further executive branch review" and are "protected by for-cause removal restrictions."[38] Compl., ¶ 87.

Under the Constitution, "the 'executive Power'—all of it—is 'vested in a President,' who must 'take Care that the Laws be faithfully executed.'" *Seila Law LLC v. Consumer Financial Protection Bureau*, 140 S. Ct. 2183, 2191 (2020) (plurality opinion) (quoting U.S. Const. art. II, § 1, cl. 1). The President "'cannot delegate [that] ultimate responsibility or the active obligation to supervise that goes with it.'" *Free Enter. Fund v. Public Company Accounting Oversight Bd.*, 561 U.S. 477, 496 (2010) (describing a "clear and effective chain of command" down from the

38 The parties do not dispute that ADR Board members are officers not employees. As officers, Board members "occupy a 'continuing' position established by law," not an "occasional or temporary" appointment. *Lucia v. SEC*, 138 S. Ct. 2044, 2051 (2018) (quoting *United States v. Germaine*, 99 U.S. 508, 511-12 (1878)); 42 U.S.C. § 256b(d)(3)(B)(i); 42 C.F.R. § 10.20. They also exercise significant authority. *See, e.g.*, 85 Fed. Reg. at 80,635-36, 80,640-42; *Freytag v. C.I.R.*, 501 U.S. 868, 881 (1991) (vesting 'officer status in "[a]ny appointee exercising significant authority"); *Edmond v. United States*, 520 U.S. 651, 662 (1997) (observing that exercise of significant authority "marks, not the line between principal and inferior officer for Appointments Clause purposes, but rather . . . the line between officer and nonofficer").

President, who in the end is politically accountable to the voters for the actions of everyone below him in the organizational chart); 1 Annals of Cong. 462, 499 (Madison) (describing a "chain of dependence" where "the lowest officers, the middle grade, and the highest will depend, as they ought, on the President," and where the President depends on "the supreme body, namely, the people").

Still, the President can appoint "subordinate officers" to help carry out his constitutional "responsibilities," because "no single person could fulfill" them. *Seila Law*, 140 S. Ct. at 2191. The Appointments Clause reflects this principle. *United States v. Arthrex, Inc.*, 141 S. Ct. 1970, 1976 (2021). It provides that:

> [The President] . . . shall nominate, and by and with the Advice and Consent of the Senate, shall appoint Ambassadors, other public Ministers and Consuls, Judges of the Supreme Court, and all other Officers of the United States, whose Appointments are not herein otherwise provided for, and which shall be established by Law; but the Congress may by Law vest the Appointment of such inferior Officers, as they think proper, in the President alone, in the Courts of Law, or in the Heads of Departments.

U.S. Const. art. II, § 2, cl. 2. The Appointments Clause hence divides officers into two categories: principal and inferior. *Morrison v. Olson*, 487 U.S. 654, 670 (1988). "Only the former are appointed subject to the advice and consent of the Senate," *Com. of Pa., Dep't of Pub. Welfare v. U.S. Dep't of Health & Hum. Servs.*, 80 F.3d 796, 801 (3d Cir. 1996), while Congress may "dispense with joint appointment" for the latter. *Arthrex*, 141 S. Ct. at 1979.

"Whether one is an 'inferior' officer depends on whether he [or she] has a superior" other than the President. *Edmond v. United States*, 520 U.S. 651, 662 (1997). If so, then the officer must be "directed and supervised at some level by others who were appointed by Presidential nomination with the advice and consent of the Senate." *Id.* at 663. Beyond this two-part guide, the Supreme Court has been careful not to create a rigid test to distinguish principal officers from

inferior ones, or to decide whether an inferior officer exceeds the permissible scope of her duties, which are "the same constitutional violation." *Arthrex*, 141 S. Ct. at 1985; *Edmond*, 520 U.S. at 661 (declining to "set forth an exclusive criterion"); *Morrison*, 487 U.S. at 671 ("We need not attempt here to decide exactly where the line falls between the two types of officers . . . . The line between 'inferior' and 'principal' officers is one that is far from clear, and the Framers provided little guidance into where it should be drawn.").

Three factors nonetheless are useful. *Id*. One "significant" factor is whether the officer has the power to "render a final decision on behalf of the United States," or whether a superior officer has discretion to review and reverse decisions. *Edmond*, 520 U.S. at 665. Relatedly, the second factor focuses on the degree of supervision/oversight vested in the superior officer (*e.g.*, the Secretary), notwithstanding the inferior officer's ability to make final decisions. *Id.* at 664; *Fleming v. United States Dep't of Agriculture*, 987 F.3d 1093, 1103 (D.C. Cir. 2021). A third "powerful tool" is the ability "to remove officers . . . without cause." *Edmond*, 520 U.S. at 664 (citing *Bowsher v. Synar*, 478 U.S. 714, 727 (1986); *Myers v. United States*, 272 U.S. 52 (1926); *Free Enter. Fund*, 561 U.S. at 477.

i. Final Decisionmaking Authority Despite Subordinate Status

There is no dispute that ADR Board members are inferior in the formal, definitional sense that they are lower in rank than many officers within HHS. They are government employees drawn in equal number from HRSA, the Centers for Medicare and Medicaid Services, and HHS' Office of General Counsel, with a non-voting member from the Office of Pharmacy Affairs. 85 Fed. Reg. 80,644. They serve in HRSA, one of eleven operating divisions under the HHS umbrella, which "provides health care to people who are geographically isolated and those who are economically

or medically vulnerable."[39] And in their capacity as Board members, their superiors include (at least) the HHS Secretary, who appoints them, and the HRSA Administrator, who selects them for panels. *Id.* at 80,632. In this sense, ADR Board members are akin to the APJs in *Arthrex*, who sat within a division of the Department of Commerce under both the Secretary and the PTO Director—that is, at the very bottom of the executive branch, with a long path to the President. Partly on this basis, the Supreme Court held that APJs resemble inferior officers in all respects other than a restriction on the Director's ability to review their decisions, which the Court severed from the statutory scheme to bring their appointments in line with the Constitution.

At the same time, although they are subordinate to other officers in the executive branch, Board members issue final decisions to resolve proceedings between covered entities and manufacturers, which the Secretary has no power to revise or reverse once rendered, 42 U.S.C. § 256b(d)(3)(C); 42 C.F.R. § 10.24(d), and which may only be formally "overturn[ed]" in federal court. 82 Fed. Reg. at 80,641; 42 C.F.R. § 10.24(d). Because their decisions cannot be stricken from the books by appeal to a principal officer within HHS, this factor cuts in favor of Sanofi's position that Board members are either principal officers or exercise powers exceeding their inferior status, as did a similar arrangement in *Arthrex* (coupled, to be sure, with a removal restriction).[40]

---

39 HRSA, Agency Overview, at 1 (Jan. 2021), *available at* https://www.hrsa.gov/sites/default/files/hrsa/about/hrsa-agency-overview.pdf (last visited Nov. 4, 2021).

40 If this factor were dispositive, then I would sever the finality provision in the 340B statute rather than hold the entire regime unconstitutional, a "tailored approach" which complies with the principle—applied in *Arthrex* itself—that "when confronting a constitutional flaw in a statute, [courts] try to limit the solution to the problem" by disregarding the "problematic portions while leaving the remainder intact." *Ayotte v. Planned Parenthood of Northern New Eng.*, 546 U.S. 320, 321 (2006); *Bank of Hamilton v. Lessee of Dudley*, 27 U.S. 492, 520 (1829) (Marshall, C.J.) (giving "full effect" to the constitution and to whatever portions of the statute are "not repugnant" to it); *Brockett v. Spokane Arcades, Inc.*, 472 U.S. 491, 504 (1985) (explaining the "normal rule that partial, rather than facial, invalidation is the required course").

ii. The Secretary's Oversight Powers

HHS responds that the ADR Board poses no constitutional infirmity because the Secretary can supervise members in other ways besides direct review, such as by revoking the Board's authority and deciding cases personally or rescinding the ADR Rule entirely. U.S. Br., at 36-37 (arguing that Sanofi "ignores all the relevant, powerful tools for control that the Secretary may exercise"). HHS also points out that the Board must follow the Secretary's procedures and policies, and members cannot impose remedies, only issue decisions. Together, according to HHS, these counterbalance the Secretary's inability to review or reverse panel decisions.

I agree with HHS, and cannot find that "[i]n all the ways that matter to the parties who appear before [an ADR panel], the buck stops with [Board members]." *Arthrex*, 141 S. Ct. at 1982. Of course, in *Arthrex*, the Supreme Court rejected a number of supervisory powers other than direct review through which the PTO Director could arguably affect the APJs' decisionmaking process: the Director could decide whether to initiate *inter partes* review in the first place, pick and choose which APJs will decide a case, or "jump in" at the last minute to vacate his original decision to institute proceedings. *Id.* at 1981. But these "machinations," the Court held, represented part of "the problem" not "the solution," because they enabled the Director to "evade a statutory prohibition on review without having him take responsibility for the ultimate decision," and "blur[red] the lines of accountability demanded by the Appointments Clause." *Id.* at 1982.

Not so here. The ADR Rule provides one clear-cut, unambiguous supervisory mechanism above all else, "for which a politically accountable officer must take responsibility." *Id.* at 1982. All panel decisions must be "submit[ted] . . . to HRSA for appropriate action regarding refunds, penalties, removal, or referral to appropriate Federal authorities," and as such, they are not self-effectuating. 42 C.F.R. § 10.24(e). When a decision reaches this stage, no statutory provisions

constrain what HHS may do with it or prohibit the agency from simply doing nothing. Even if HHS agrees with a decision, by all accounts (including its own regulations), it cannot impose a refund or penalty without referring the manufacturer or covered entity to the OIG, which affords its own procedural protections. *See, e.g.*, 85 Fed. Reg. at 80,642 ("Therefore, when appropriate, the 340B ADR Panel may make *recommendations* to HRSA for sanctions, including referrals to the HHS [OIG] *for its consideration* of [CMPs]."") (emphasis added). And the President appoints both the HHS Secretary and the HRSA Administrator, the former with Senate confirmation and the latter without it, one of whom must be responsible for deciding how to proceed once the Board adjudicates a claim. *Accord Astra*, 563 U.S. at 114 ("Congress placed the Secretary (acting through her designate, HRSA) in control of § 340B's drug-price prescriptions."). In other words, though ADR Board members issue final decisions, the Secretary or HRSA Administrator need not take further action—at their election and in their sole discretion—if they "catch wind of an unfavorable ruling" or otherwise disagree with how the Board has decided a claim, which meaningfully constrains the Board's power and limits the consequences of its decisions—and does so free of accountability-clouding maneuvers. *Arthrex*, 141 S. Ct. at 1981. This regulatory scheme, which leaves "the form of enforcement . . . open," is designed "to permit HHS maximum flexibility in determining what is appropriate given the specific facts of each situation," if anything.[41] 85 Fed. Reg. at 80,642.

A well-defined division between determining the merits of a 340B claim (as the Board does) and enforcing the determination (as the Secretary or HRSA Administrator may do) not only sets this case apart from *Arthrex*, but puts it on par with *Kalaris v. Donovan*, 697 F.2d 376 (D.C. Cir. 1983), where compensation orders issued by the Department of Labor Review Board required

41 This would appear to impact the precedential value of Board decisions.

"resort" to a district court for implementation. *Id.* at 388. By the same token, separating the right from the remedy is a sufficient "means of countermanding [a] final decision already on the books," contrary to *Arthrex*, where the PTO Director was essentially limited to a handful of pre-decision interventions. 141 S. Ct. at 1982. Here, indeed, the Secretary or HRSA Administrator can prevent any legal consequences that might flow from an adverse judgment, notwithstanding its finality, which effectively gives a principal officer "last-word capacity." *Lucia v. SEC*, 138 S. Ct. 2044, 2054 (2018). In substance, this case is also like *Fleming*, where "the Secretary may, at his election, step in and act as final appeals officer in any case" under the implementing regulation. 987 F.3d at 1103 (citing 7 C.F.R. § 2.12). The point is that neither the Secretary nor the HRSA Administrator is obligated to act on a final judgment by the Board, which is a genuine and—importantly—transparent limit on the Board's power to issue them. *Accord Tucker v. C.I.R.*, 676 F.3d 1129, 1134 (D.C. Cir. 2012) ("The degree of discretion enjoyed by the officeholder is clearly an element in the mix."). Because the Board's decisions are not self-effectuating, but must be enforced (if at all) by other principal officers in HHS, this factor cuts in favor of the Government.[42]

---

42 HHS emphasizes other supposed oversight powers which are not meaningful and would not be sufficient on their own to constrain the authority of the Board. The Secretary cannot rescind the ADR Rule without replacing it with another, since Congress mandated dispute resolution through legislation. The Secretary also cannot rescind the ADR Rule without complying with the APA's procedural requirements for new agency action, including notice and comment, which (as evidenced by this case) can take some time. *Friends of Animals v. Bernhardt*, 961 F.3d 1197, 1205-06 (D.C. Cir. 2020) ("It is, of course, black-letter administrative law that ordinarily an agency that promulgates a rule under § 553's auspices must use the same procedure to revoke that rule.") (citing *Clean Air Council v. Pruitt*, 862 F.3d 1, 9 (D.C. Cir. 2017)); 5 U.S.C. § 551(5) (defining "rule making" to include "agency process for formulating, amending, or repealing a rule"); *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 101 (2015) (explaining that § 551 "mandate[s] that agencies use the same procedures when they amend or repeal a rule as they used to issue the rule in the first instance"). Moreover, while the Secretary seemingly could revoke her "express, written delegation of authority" to the ADR Board to adjudicate cases, 42 C.F.R. § 10.3 (creating the Board), and decide them herself, 42 U.S.C. § 256b(d)(3)(B)(i) (directing the Secretary to simply "designate . . . a decision-making official or decision-making body" to resolve 340B disputes), nothing in the ADR Rule *as written* authorizes the Secretary to personally handle cases in this way, contrary to other cases where courts found such power sufficient. *See, e.g.*, *Fleming*, 987 F.3d at 1103. Finally, HHS is incorrect that inherent substantive limitations on the Board's decision-making authority flow from Congress'

iii. Removal Power

The third significant factor is whether the inferior officer is subject to removal by a higher executive branch official who is herself a principal officer. *Morrison*, 487 U.S. at 671-72. The parties sharply dispute which way this factor goes. Sanofi emphasizes that the HRSA Administrator may remove ADR Board members from ADR panels in particular cases, but only for cause, such as a dispute-specific conflict of interest. San. Br., at 60-68. HHS responds that Sanofi conflates reassignment from a panel with removal from the Board altogether, and insists that the Secretary faces no limitations on her power to determine the Board's composition, as "members serve at [her] pleasure."[43] U.S. Br., at 36.

By emphasizing reassignment from a panel, Sanofi shifts focus to the wrong officer, the wrong power, at the wrong level. Only removal *from the Board* matters in the sense of the Constitution because officers are appointed to *federal service* in the first instance as Board members, notwithstanding their other government employment,[44] and can only be terminated from federal service *entirely*, *i.e.*, as Board members, if they are dismissed in that capacity. *Arthrex* readily supports this distinction. There, the Supreme Court rejected the government's argument that the PTO Director's ability to remove an APJ "from his judicial assignment without cause" constituted a meaningful degree of supervision or control. 141 S. Ct. at 1982. Instead, the Court

---

instructions or the ADR Rule. Neither the authorizing statute nor the implementing regulation appears to constrain the Board in this regard.

43 The statute authorizes the Secretary to appoint and delegate authority to the Board, and the ADR Rule authorizes the HRSA Administrator to assign panelists to particular cases as well as reassign them for-cause. Neither the statute nor the ADR Rule expressly restricts the Secretary from removing Board members from federal service in that capacity or from reassigning panelists, regardless of the Administrator's authority. 85 Fed. Reg. 80,644.

44 It is not relevant whether Board members' other government positions are protected with for-cause removal, so long as their Board member service is not.

held, "the threat of removal from federal service entirely" is the relevant consideration under the Appointments Clause. *Id.* And since *that* power was subject to for-cause protection, APJs were unconstitutionally appointed—the exact opposite of the situation at hand. Where a principal officer who answers directly to the President, such as the Secretary, may freely remove a subordinate, such as an ADR Board member, the Supreme Court has recognized that the President technically exercises his removal authority over those inferior officers through his "alter ego," thereby ensuring accountability throughout the organizational chart. *See, e.g.*, *Myers*, 272 U.S. at 133 (referring to "alter ego" of President); *Morrison*, 487 U.S. at 692 (describing Attorney General as effectively President's alter ego for removal purposes); *Ex parte Hennen*, 38 U.S. 230, 259-60 (1839). Under Sanofi's contrary interpretation, the President and the Senate would need to jointly choose ADR panelists for every 340B adjudication, which would not only "become inconvenient," but border on the impossible. *United States v. Germaine*, 99 U.S. 508, 510 (1878). The HRSA Administrator's reassignment power does not *ipso facto* translate into for-cause removal protection under the Appointments Clause.

Further, while the HRSA Administrator's reassignment power is partial, the Secretary's removal power is complete. Neither the authorizing statute nor the ADR Rule limits when or why the Secretary may terminate or replace Board members, and as such, she has *carte blanche* to handpick and then re-pick them.[45] *Kalaris*, 697 F.2d at 389 ("The general and long-standing rule is that, in the face of statutory silence, the power of removal presumptively is incident to the power of appointment."); *Free Enter. Fund*, 561 U.S. at 509 ("Under the traditional default rule, removal is incident to the power of appointment."); *Hennen*, 38 U.S. at 259 (same); *Parsons v. United States*, 167 U.S. 324, 331 (1897) (same); *Keim v. United States*, 177 U.S. 290, 294 (1900) (same);

45 Sanofi, for its part, has not pointed to any other statutory or regulatory constraint on the Secretary's ability to remove Board members "from federal service entirely." *Arthrex*, 141 S. Ct. at 1982.

Sampson v. Murray, 415 U.S. 61, 70 & n.17 (1974) (same). This is likewise true of the Secretary's power to reassign panelists for any reason or no reason, even though that power is not mentioned in the ADR Rule. *Cafeteria & Restaurant Wkrs Union, Local 473 v. McElroy*, 367 U.S. 886, 896 (1961) ("[G]overnment employment, in the absence of legislation, can be revoked at the will of the appointing officer."); *Nat'l Treasury Employees Union v. Reagan*, 663 F.2d 239, 247 (D.C. Cir. 1981) ("[T]his continues to be the rule to the present day."). Accordingly, I have little doubt that ADR Board members remain subject to at will removal and reassignment by the Secretary, and this factor points decidedly in HHS' favor. *Morrison*, 487 U.S. at 671 (holding that removal power necessarily indicates that an officer is "to some degree 'inferior' in rank and authority").

iv. Weighing the Factors

Because either the Secretary or HRSA Administrator may decline to pursue a refund/sanction once the Board issues a final decision, and the Secretary at all times retains removal power over Board members, the Board's structure does not violate Article II and Board members do not exercise power in a way that conflicts with the design of the Appointments Clause. Board members do not decide § 340B claims "without the kind of appointment the Clause requires." *Lucia*, 138 S. Ct. at 2055.

The balance of case law is in accord: a meaningful and transparent degree of supervision plus at-will removal generally makes an inferior officer's non-Presidential appointment constitutional. In *Free Enter. Fund*, for instance, the Supreme Court upheld the SEC's ability to appoint members of the Public Oversight Accounting Oversight Board ("PCAOB"), which regulates the "entire industry" of accounting firms with "expansive powers." 561 U.S. at 485. According to the Court, "[g]iven that the [SEC Commission] is properly viewed [after striking a for-cause removal provision] as possessing the power to remove Board members at will, and given

the Commission's other oversight authority, we have no hesitation in concluding that under *Edmond* the [PCAOB] members are inferior officers." *Id.* at 510. The "other oversight authority" included the power to approve or alter the PCAOB's penalties, similar enough to the Secretary's discretion here not to act on Board decisions. *Id.* at 486. The Court upheld the composition of the PCAOB despite the fact that, unlike this case, "the [PCAOB] *itself* [could] issue severe sanctions in its disciplinary proceedings, up to and including the permanent revocation of a firm's registration, a permanent ban on a person's associating with any registered firm, and money penalties of $15 million ($750,000 for a natural person)." *Id.* at 485-86 (emphasis added).

While the degree of oversight in *Free Enter. Fund* resembled direct review, that is not strictly necessary under the Appointments Clause. An example is *Intercollegiate Broadcasting System, Inc. v. Copyright Royalty Bd.*, 684 F.3d 1332 (D.C. Cir. 2012), where the D.C. Circuit severed a removal restriction on the appointment of Copyright Royalty Judges ("CRJs"), then held that "the threat of removal satisfies us that [their] decisions will be constrained to a significant degree by a principal officer," the Librarian of Congress, even though the decisions "will still not be directly reversible." *Id.* at 1341. Unfettered removal power plus *some other* significant oversight authority ensured that the Librarian could sufficiently "direct," "supervise," and exert "control" over CRJs—such authority being the mere ability to "provide substantive input on non-factual issues," whereas here it is the power to decide whether to enforce/effectuate Board decisions. *Id.* (quoting *Edmond*, 520 U.S. at 662-64, for support). If the appointment of CRJs passes constitutional muster because the Librarian could provide some input on some matters, then so must the appointment of ADR Board members when the Secretary may decline to pursue a penalty altogether. Another example is *Fleming*, where the D.C. Circuit rejected out of hand the proposition that "an inferior officer's decisions must be subject to review by a principal officer"

for the officer to be constitutionally appointed by someone other than the President, and in turn "had little difficulty classifying the [USDA's] ALJs as inferior officers." 987 F.3d at 1103.

Finally, as already discussed, *Arthrex* supports HHS' position. The Supreme Court first observed that the "threat of removal from federal service entirely" is a "meaningful" degree of control and the relevant inquiry in the sense of the Appointments Clause—not whether the officer in question may be assigned or reassigned from certain tasks with cause. 141 S. Ct. at 1982. Additionally, the PTO Director in *Arthrex* could not oversee APJs except to the extent that he could intervene in limited ways before they issued decisions. The *combination* of these provisions, coupled with the untransparent nature of the "machinations" in which the Director could engage to exercise control, posed the primary constitutional problem. Neither scenario is present here: there is a greater degree of oversight (*i.e.*, the Secretary need not pursue a sanction against a manufacturer regardless of what the Board says in a decision), and there is no for-cause removal protection (*i.e.*, the Secretary may terminate Board Members from federal service in that capacity entirely for whatever reason or no reason at all).

Accordingly, in every respect "save the insulation of their decisions from review within the Executive Branch, [ADR Board members] appear to be inferior officers—an understanding consistent with their appointment in a manner permissible for inferior but not principal officers." *Id.* at 1986. And even then, at least two principal officers who answer to the President may negate a Board decision by declining to pursue the decision any further. The Appointments Clause does not demand more.

C. Compliance with Article III

Finally, Sanofi argues that the ADR Rule violates Article III by granting ADR panels the power to adjudicate matters involving private rights. Article III commands that "[t]he judicial

Power of the United States, shall be vested in one supreme Court, and in such inferior Courts as the Congress may from time to time ordain and establish." *Id.* § 1. Under "the basic concept of separation of powers . . . the 'judicial Power' . . . can no more be shared" with another branch than "the Chief Executive, for example, can share with the Judiciary the veto power, or the Congress share with the Judiciary the power to override a Presidential veto." *United States v. Nixon*, 418 U.S. 683, 704 (1974) (quoting U.S. Const. art. III, § 1). A statute or regulation thus violates Article III if it "confer[s] the Government's 'judicial Power' on entities outside Article III." *Stern v. Marshall*, 564 U.S. 462, 484 (2011).

When determining whether a proceeding involves an exercise of judicial power, the Supreme Court's precedents distinguish between "public rights" and "private rights." *Executive Benefits Ins. Agency v. Arkison*, 573 U.S. 25, 32 (2014) (citations omitted). Congress may not "withdraw from judicial cognizance" private rights, or "any matter which, from its nature, is the subject of a suit at the common law, or in equity, or admiralty." *Murray's Lessee v. Hoboken Land & Improvement Co.*, 59 U.S. 272, 284 (1856). In other words, Article III judges must decide matters "made of the stuff of the traditional actions at common law tried by the courts at Westminster in 1789." *Stern*, 564 U.S. at 484 (quotations and citation omitted).[46]

But Congress may constitutionally assign cases involving "public rights" to non-Article III courts. Public rights cases arise when there is a dispute "between the Government and persons subject to its authority in connection with the performance of the constitutional functions of the executive or legislative departments." *Crowell v. Benson*, 285 U.S. 22, 50 (1932). More

46 Notably, however, even when private rights are at stake, Article III does not require federal courts to "perform every stage of adjudication." *Kalaris*, 697 F.2d at 396; *Crowell v. Benson*, 285 U.S. 22, 47 (1932) (upholding scheme where agency conducted factfinding, in part because conclusions were subject to subsequent judicial review in Article III courts and because findings of fact were specialized and narrow); *Stern*, 564 U.S. at 498 n.6 (understanding *Crowell* to stand for this proposition).

straightforwardly, "what makes a right 'public' rather than private is that the right is integrally related to particular Federal Government action." *Stern*, 564 U.S. at 490-91; *Ex parte Bakelite Corp.*, 279 U.S. 438, 451 (1929) (applying exception to matters "arising between the government and others, which from their nature do not require judicial determination and yet are susceptible of it"); *Granfinanciera, S.A. v. Nordberg*, 492 U.S. 33, 54-55 (1989) ("If a statutory right is not closely intertwined with a federal regulatory program Congress has power to enact, and if that right neither belongs to nor exists against the Federal Government, then it must be adjudicated by an Article III court.").

The public rights exception can be expansive. *Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365, 1373 (2018) ("[Our] precedents have given Congress significant latitude to assign adjudication of public rights to entities other than Article III courts."). Based on the "varied formulations . . . in the [Supreme] Court's cases," an Article III court need not adjudicate a claim in the first instance if it may be pursued "only by grace of the other branches," it "historically could have been determined exclusively by" those branches, it derives or "flow[s] from a federal statutory scheme," it is "completely dependent upon" federal law for its creation, it "depends upon the will of Congress," it is limited to "a particularized area of law" for which Congress has devised an "expert and inexpensive method . . . particularly suited" to address the question and "specially assigned to that task," or "resolution of the claim by an expert Government agency is deemed essential to a limited regulatory objective within the agency's authority." *Stern*, 564 U.S. at 489-94 (quotations and citations omitted); *Atlas Roofing Co. v. Occupational Safety and Health Review Comm'n*, 430 U.S. 442, 458 (1977) (applying exception "where the Government is involved in its sovereign capacity under . . . [a] statute creating enforceable public rights," while holding that "[w]holly private tort, contract, and property cases,

. . . are not at all implicated"); *Thomas v. Union Carbide Agric. Prod. Co.*, 473 U.S. 568, 571-75 (1985) (applying exception to a data-sharing arrangement because "[a]ny right to compensation . . . results from [the statute] and does not depend on or replace a right to such compensation under state law").

The inquiry into whether a right is public is also "pragmatic." *Commodity Futures Trading Comm'n v. Schor*, 478 U.S. 833, 853 (1986). In conducting the inquiry, I look to the substance, not the form, of "what Congress has done" to determine if there is a "substantial threat to the separation of powers," while keeping in mind that the existence of a private right requires more "searching" "examination," not automatic invalidation of the non-Article III scheme adjudicating it. *Id.* at 851 (weighing "a number of factors . . . , with an eye to the practical effect that the congressional action will have on the constitutionally assigned role of the federal judiciary").

As a threshold matter, the parties dispute how to construe the subject matter of the ADR proceedings. *See, e.g.*, *Granfinanciera*, 492 U.S. at 56 (emphasizing both the general right to restructure debtor-creditor relations, which "may well be" public, and the specific right associated with state law breach of contract, which is "paradigmatic[ally]" private). At a high level of generality, Sanofi suggests that the underlying dispute is a transfer of goods pursuant to a contract (like specific performance), or for a refund/credit consistent with the contract price (like damages for breach). San. Br., at 74-77 (arguing that the claim "is effectively a state law contract claim—with there even being a contract (the PPA) that requires offering 340B pricing to covered entities"). According to HHS, on the other hand, the dispute involves a claim for a drug discount, which is a novel entitlement that would not exist but for the 340B statute.

Based on these differences, Sanofi emphasizes the right § 340B *infringes*—control over its personal property—while HHS emphasizes the privilege the statute *provides*—drug purchases at

a ceiling price. *Compare* Sanofi Br., at 75-76 (stating that HHS "misunderstands the nature of the rights at issue" because "[a]lthough Section 340B creates covered entities' entitlement to drug discounts, it is *Sanofi's* private [property] rights that are at stake") (citing *Newland v. Marsh*, 19 Ill. 376, 383 (1857) ("The legislative power . . . cannot directly reach the property or vested rights of the citizen, by providing for their forfeiture or transfer to another, without trial and judgment in the courts."))), *with* U.S. Rep. Br., at 35-36 & n.17 ("Sanofi is wrong. The private/public rights inquiry focuses on the *claim* being adjudicated . . . not whether property changes hands through the disposition.").

I agree with HHS that the point of focus when applying the public rights exception must be the asserted claim, not the incidental property right. This follows from the language the Supreme Court has used to describe the doctrine. In *Stern*, for example, the Court plainly defined public rights as those "in which the *claim at issue* derives from a federal regulatory scheme." 564 U.S. at 490 (emphasis added). HHS' interpretation is also consistent with key case law, where the Court has permitted non-Article III adjudication despite the presence of an underlying—and often historically significant—private property interest. For instance, in *Thomas*, the Court upheld binding agency arbitration for compensation disputes between first-mover registrants of a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") and "me too" registrants, who use the first-mover's safety data for a fee to streamline regulatory approval. 473 U.S. at 571. Congress enacted the scheme because it recognized "a limited proprietary interest" in the data, which by definition would *bar* it under Sanofi's interpretation.

Sanofi attempts to distinguish *Thomas* by pointing out that, "[a]s a matter of state law," a FIFRA registrant "extinguished" its "property rights" in the data by disclosing it to the government on the knowledge that others could use it. *Id.* at 584. Even if the ruling in *Thomas* turned on that

forfeiture—which is doubtful given the Court's reluctance to "adopt formalistic and unbending rules" in this area, *Schor*, 478 U.S. at 851—that hardly tips the scale towards Sanofi. Sanofi too extinguished the relevant attribute of its property interest in its drugs (exclusive control over the sales price/purchaser) by opting into the 340B Program with notice of the discount regime, on the condition that it complies with agency rules, and so as to obtain access to Medicaid and Medicare Part B. Relatedly, "as a personal right, Article III's guarantee of an impartial and independent federal adjudication is subject to waiver, just as are other personal constitutional rights that dictate the procedures by which civil and criminal matters must be tried." *Schor*, 478 U.S. at 848 (collecting cases); *Northern Pipeline*, 485 U.S. at 80 (deeming absence of consent to initial adjudication in non-Article III court a significant factor).

Oil States also supports HHS' focus on the claim at issue rather than the property interest at stake. There, the Court upheld the constitutionality of *inter partes* agency review for patents despite the fact that, once issued, a patent becomes "the private property of the patentee" and confers a lucrative, decades-long monopoly in the relevant market. 138 S. Ct. at 1375. While permitting non-Article III adjudication in the PTO, the Court cautioned that its holding "should not be misconstrued as suggesting that patents are not property for purposes of the Due Process Clause or the Takings Clause." *Id.* at 1379; *Florida Prepaid Postsecondary Ed. Expense Bd. v. College Savings Bank*, 527 U.S. 627, 642 (1999) ("Patents [ ] have long been considered a species of property."); *James v. Campbell*, 104 U.S. 356, 358 (1882). Together, these cases show that the Supreme Court has historically permitted Congress to set up non-Article III adjudicatory methods in agencies even if they "surely determine liabilities of individuals," including private property rights. *Thomas*, 473 U.S. at 589; *Block v. Hirish*, 256 U.S. 135 (1921) (construing federal landlord tenant law as a public right); *Ex parte Bakelite*, 279 U.S. at 447 (same, but tariff protections against

a competitor); *Crowell*, 285 U.S. at 51-53 (displacing traditional cause of action affecting a preexisting relationship based on a common law contract for hire); *Schor*, 478 U.S. at 853 (permitting agency adjudication even though "counterclaim asserted . . . [was] a 'private' right for which state law provides the rule of decision" and was therefore "at the 'core' of matters normally reserved to Article III courts").

Turning to the nature of the claim at issue, it falls squarely on the public rights side of the line. Sanofi focuses almost exclusively on the fact that PPAs are contracts controlling how it alienates its property, as if for that reason alone they must have been "tried by the courts at Westminster in 1789." *Stern*, 564 U.S. at 484 (quotations and citation omitted). This contention is obviously flawed. For one thing, a PPA originates in a relationship with the federal government, and cannot exist outside of that. *Astra*, 563 U.S. at 113-14. For another, the "form contract," which HHS unilaterally "compose[s]" and Sanofi signs with the Government, not covered entities, is "the opt-in mechanism" for the 340B Program, "like the Medicaid Drug Rebate Program agreements." *Id.* at 115. For another, PPAs are not akin to the "[w]holly private" contracts common to the common law. *Atlas Roofing*, 430 U.S. at 458; *Thomas*, 473 U.S. at 587 ("[P]ractical attention to substance rather than doctrinaire reliance on formal categories should inform application of Article III."). PPAs "simply incorporate statutory obligations and record the manufacturers' agreement to abide by them," they are not initiated by a private party or bargained for, they "contain no negotiable terms," and even if they involve third-party beneficiaries such as covered entities, there is no third-party private cause of action to enforce them. *Astra*, 563 U.S. at 118 (stating that covered entities may not evade the ADR process by invoking PPAs directly in court). It would run further afield of well-established law to declare that PPAs take the ADR Rule beyond the scope of the public rights doctrine, and "from [their] nature" must be decided by a federal court, when they

are "one and the same" as § 340B itself, a suit based on an "HHS-drug manufacturer agreement [] is in essence a suit to enforce the [340B] statute," and both must receive "the same" "treatment" no matter "the clothing in which [manufacturers] dress their claims." *Id.* at 114, 118 (quoting *Tenet v. Doe*, 544 U.S. 1, 8 (2005)). Tellingly, in this respect, Sanofi bases its Article III challenge to the ADR Rule on the allegation that *the statute* risks its core private rights, not that any independent substantive provision or obligation in the PPA does so.

Setting aside the PPAs, Sanofi cannot point to any state law analog which the ADR Rule either replaces or depends on for a rule of decision. That is so because, under state law, covered entities do not have rights in drugs sold at 340B prices. Like the first-mover registrants in *Thomas*, "[a]ny right to compensation [in this case] . . . results from [the federal statute alone]." 473 U.S. at 584; *cf. Schor*, 478 U.S. at 854 (stating that rights with a "state law character" "were historically the types of matters subject to resolution by Article III courts).

The claim at issue in an ADR proceeding also "arises in the context of a federal regulatory scheme that virtually occupies the field," *Thomas*, 473 U.S. at 600 (Brennan, J., concurring in the judgment), and "is so closely integrated into a public regulatory scheme as to be a matter appropriate for agency resolution with limited involvement by the Article III judiciary." *Granfinanciera*, 492 U.S. at 55 (quoting *Thomas*, 473 U.S. at 593-94). This is particularly true because the 340B Program draws heavily on another federal scheme, the Medicaid Drug Rebate Program. "Congress made HHS administrator of both [Programs], and '[t]he interdependent nature of [them]' means that an adjudication of rights under one program must proceed with an eye towards any implications for the other." *Astra*, 563 U.S. at 120 (citation omitted). "Far from assisting HHS, suits [proceeding directly in federal court] would undermine the agency's efforts to administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis."

Id. (holding that, "with HHS unable to hold the control rein, the risk of conflicting adjudications would be substantial"); *Schor*, 478 U.S. at 852 (affirming SEC jurisdiction over "common law counterclaims" which are "private" and "for which state law provides the rule of decision," and in the process upholding "a reparations procedure through which disgruntled customers of professional commodity brokers could seek redress for the brokers' violations of [SEC] regulations").

By the same token, the ADR Rule deals with "a particularized area of law," which consists exclusively of overcharges, duplicate discounting, and drug diversion. These types of claims represent "a class of questions of fact which are peculiarly suited to examination and determination by [the] administrative agency specially assigned to" administering the 340B Program. *Crowell*, 285 U.S. at 46. ADR panels do not have unlimited jurisdiction within this narrow context either: they are confined to issues that arise out of a claim or defense and that exceed $25,000 in a twelve-month period. 85 Fed. Reg. at 80,634; 42 C.F.R. 10.21(b); *cf. Northern Pipeline*, 458 U.S. at 85 (finding unconstitutional jurisdiction of bankruptcy courts extending broadly to "all civil proceedings arising under title 11 or arising in or related to cases under title 11").

If any doubt remains, *Astra* conclusively puts it to rest. There, the Supreme Court held that a covered entity must comply with the ADR Rule before going to court, an implicit affirmation of the HHS' lawful authority to adjudicate such disputes in the first instance. *Astra*, 563 U.S. at 113 ("[S]uits by 340B entities to enforce ceiling-price contracts running between drug manufacturers and the Secretary of HHS are incompatible with the statutory regime."). The Court wrote that Congress "vested authority to oversee compliance with the 340B Program in HHS," and "[u]nder ADR procedures . . . HRSA will reach an 'administrative resolution' that is subject to judicial review under the [APA]," *id.* at 116, observations which would not make sense if the adjudicatory

scheme producing the "administrative resolution" were unconstitutional. Indeed, it is difficult to imagine that the Court would require regulated entities to comply with a constitutionally defective process just because Congress made it mandatory in legislation. Similarly, in *Am. Hosp.*, a court in the Northern District of California held that it would "short-circuit the foundational regime that Congress has enacted" if covered entities could proceed to court notwithstanding the ADR Rule, that the judiciary's "role comes only after the parties have participated in [the] ADR process," and that "Congress made explicit that 340B Program violations are to be first adjudicated by HHS." 2021 WL 616323, at *6.

As a last resort, Sanofi suggests that the ADR Rule violates Article III because it empowers ADR panels to function too much like courts, *i.e.*, it shares certain salient characteristics with the exercise of judicial power. But that contention is a nonstarter. The Supreme Court "has never adopted a 'looks like' test to determine if an adjudication has improperly occurred outside of an Article III court," since "[t]he fact that an agency uses court-like procedures does not necessarily mean it is exercising the judicial power." *Oil States*, 138 S. Ct. at 1378 (rejecting argument that *inter partes* patent review "violates Article III because it shares every salient characteristic associated with the exercise of the judicial power," including "motion practice . . . ; discovery, depositions, and cross-examination of witnesses; introduction of evidence and objections based on the Federal Rules of Evidence; and an adversarial hearing before the Board") (quotations and citation omitted); *Freytag v. C.I.R.*, 501 U.S. 868, 891 (1991) (upholding Tax Court despite "exclusively judicial role" and functions that "closely resemble those of the federal district courts"); *Williams v. United States*, 289 U.S. 553, 563 (1933) (rejecting notion that tribunal exercises Article III judicial power simply because it is "called a court and its decisions called judgments"); *Murray's Lessee*, 59 U.S. at 281 (permitting the Treasury Department to conduct

"final and binding" audits outside of an Article III court). I therefore find that the ADR Rule does not "withdraw from judicial cognizance" that which only the judiciary may constitutionally exercise.[47] *Schor*, 478 U.S. at 855. The ADR Rule survives Sanofi's challenges under the APA, Article II, and Article III.

IV. THE VIOLATION LETTERS

Approximately four months before issuing the AO, HHS informed manufacturers that it was "considering whether [their contract pharmacy] polic[ies] constituted a violation of § 340B." Administrative Record ("AR"), at 7627. Forewarned, Sanofi implemented its Integrity Initiative, and Novo followed suit. Sanofi's policy permits shipments to in-house pharmacies or one contract pharmacy per covered entity without conditions, but requires covered entities to submit claims-level data if they wish to use multiple contract pharmacy arrangements, while Novo's policy permits one contract pharmacy per covered entity as a rule and more than one if it deems the risk of fraud or abuse sufficiently low. Nine months later, in response, HHS sent the Violation Letters.[48] After reviewing "complaints . . . from covered entities" as well as Plaintiffs' rationales, past agency guidance, and the 8,000-page administrative record, HHS concluded that Plaintiffs overcharged covered entities contrary to § 340B. *Id.* According to HHS, "[n]othing in the 340B statute grants a manufacturer the right to place conditions" or "industry-wide, universal restrictions" on offers to covered entities, and in the PPAs they signed, Plaintiffs agreed to "ensure that the 340B ceiling

47 It is not lost on the Court that Sanofi's position would call into question commonplace features of the administrative state. "Congress has been creating quasi-judicial boards subject to Executive control for years, and the courts have not previously prevented them from doing so. To do so now would be to turn the clock back on at least a century of administrative law." *Kalaris*, 697 F.2d at 401 (quotations and citation omitted).

48 *See, e.g.*, HRSA, Letter to Sanofi Regarding Sales to Covered Entities through Contract Pharmacies (May 17, 2021), *available at* https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hrsa-letter-sanofi-covered-entities.pdf (last visited Nov. 4, 2021).

price is available to all covered entities," presumably regardless of the dispensing mechanism they choose to use. *Id.* HHS provided Plaintiffs with a short window in which they could devise a plan to come into compliance or else face CMPs, which the agency has yet to impose but recently referred to the OIG.[49] Plaintiffs argue that the Violation Letters exceed statutory authority, and are contrary to law, because they advance an impermissible construction of § 340B. 5 U.S.C. § 706(2)(C). Plaintiffs also argue that the Letters constitute an unconstitutional taking in violation of the Fifth Amendment. Finally, Plaintiffs argue that the Letters are arbitrary and capricious, mainly because they represent an unexplained inconsistency in HHS' position. *Id.* § 706(2)(A).

A. Statutory Interpretation Challenges Under the APA

I begin with Plaintiffs' statutory interpretation challenges. *Int'l Union, United Auto., Aerospace & Agr. Implement Workers of Am. v. Brock*, 783 F.2d 237, 245 (D.C. Cir. 1986) ("[W]hen a legal challenge focuses on an announcement of a substantive statutory interpretation, courts are emphatically qualified to decide whether an agency has acted outside of the bounds of reason."); *City of Arlington, Tex. v. F.C.C.*, 569 U.S. 290, 297 (2013) ("No matter how it is framed, the question a court faces when confronted with an agency's interpretation of a statute it administers is always, simply, *whether the agency has stayed within the bounds of its statutory authority*.") (emphasis in original). Plaintiffs explain that the Violation Letters exceed HHS' authority under § 340B and are contrary to law for three reasons: Congress did not intend to permit contract pharmacy arrangements in the first place, never mind in unlimited numbers; § 340B provides Plaintiffs with the authority to unilaterally place conditions on 340B offers in any event;

49 The question whether manufacturers may require covered entities to pay the cost of delivery to multiple contract pharmacies is not before me. Although Plaintiffs vaguely allude to this type of expense, they have neither officially objected to it, nor has HHS formally taken a position on it. Should a manufacturer implement a policy requiring covered entities to pay shipping costs, or should HHS commence an enforcement action banning manufacturers from doing so, the parties may bring a separate challenge.

and the term "overcharge" in the 340B statute does not encompass restrictive "practices," such as Plaintiffs' policies, but only erroneous "prices." For the following reasons, I find that (1) contract pharmacy arrangements are consistent with the 340B statute, (2) there is no statutory support for Plaintiffs' policies, which HHS properly deemed impermissible, and (3) Plaintiffs' policies overcharge covered entities in the sense of § 340B. At the same time, because I find that it is not appropriate for this Court to decide in the first instance, based on the complex 340B landscape, whether the statute permits multiple or unlimited contract pharmacies, I partially vacate and remand the Violation Letters for further consideration consistent with this Opinion.

i. Preliminary Matters

1. The Violation Letters Are Reviewable Final Agency Action

As a threshold issue, under the APA, only "[a]gency action made reviewable by statute and final agency action for which there is no adequate remedy in a court" is subject to judicial review. 5 U.S.C. § 704. The parties do not dispute that the Violation Letters constitute reviewable final agency action. U.S. Opp., at 39; San. Opp., at 31 n.13. Whether the Letters could be construed as pre-enforcement proceedings or actual enforcement, I am satisfied that they are ripe for my consideration. *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997) (holding that final agency action "[m]arks the consummation of the agency's decisionmaking process" and "by which rights or obligations have been determined, or from which legal consequences will flow"); *Ocean Cty. Landfill Corp. v. EPA*, 631 F.3d 652, 655 (3d Cir. 2011); *Tomasi v. Twp. of Long Beach*, 364 F. Supp. 3d 376, 390 (D.N.J. 2019). Essentially, "[n]othing in the letter[s] indicate[] that the [HHS'] statements and conclusions are tentative, open to further consideration, or conditional." *City of Dania Beach v. FAA*, 485 F.3d 1181, 1188 (D.C. Cir. 2007); *Bimini Superfast Operations LLC v. Winkowski*, 994 F. Supp. 2d 106, 117 (D.D.C. 2014) ("Having definitively declared the illegality

of Plaintiff's activities, any further agency action—if Plaintiff chooses to engage in it—comes at the enforcement stage. There is no indication that any such enforcement process would change CBP's legal position . . . given the purely legal nature of [it].").

2. The Violation Letters Are Separate from the AO

Plaintiffs attempt to tie the Violation Letters to the AO, urging the Court to set the Letters aside insofar as the AO no longer has legal effect. San. Opp., at 22; Novo Br., at 34-43. Yet, in Plaintiffs' own words, (1) the Letters are "not as explicit as the [AO] was in conceding that § 340B unambiguously prohibits [their] program[s]," (2) they "abandon" certain aspects of the AO, such as a focus on agency law, while "fail[ing] to acknowledge and explain this shift," San. Opp., at 25, (3) they never mention the AO, *id.* at 34, (4) HHS began the investigation leading up to the Letters months before it issued the AO, *id.* at 25-26, 35, (5) there is an 8,000-page administrative record supporting the Letters, Novo Rep. Br., at 21, (6) the Letters are specific enforcement actions based on past conduct while the AO is a general agency policy regulating future conduct, and (7) the AO concludes in no uncertain terms that covered entities may use unlimited contract pharmacy sites whereas the Violation Letters are not as explicit. Because there are considerable differences between the Letters and the AO, they do not rise or fall together, as the *Eli Lilly* Court similarly concluded. 2021 WL 5039566, at *14 ("Unlike the [AO], HRSA's determination in the May 17 Letter does not rely on a general, overarching requirement on behalf of manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies. Rather, the Letter is limited to the finding that Lilly's unilaterally adopted policy . . . violates . . . . the 340B statute.").

3. Deference

Satisfied that I may review the Letters at this time, I must next "determine what deference, if any," to accord HHS' construction of the 340B statute. *De Leon-Ochoa v. Att'y Gen.*

of U.S., 622 F.3d 341, 348 (3d Cir. 2010). Usually, when reviewing an agency's interpretation of a statute it administers, I would apply *Chevron* deference. *Chevron v. U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). This involves a familiar two-step inquiry. "First, always, is the question whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter." *Id.* at 842. In determining Congress' intent, a court employs "traditional tools of statutory construction." *Id.* at 843 n.9. "If, however, Congress has not directly addressed the precise question at issue, the court does not simply impose its own construction on the statute, as would be necessary in the absence of an administrative interpretation." *Id.* at 843. The court instead proceeds to step two, where "the question . . . is whether the agency's answer is based on a permissible construction." *Id.* At this stage, "a court may not substitute its own construction . . . for a reasonable interpretation made by the administrator of an agency," *id.* at 844, and to pass muster, the agency interpretation need not be "the only possible interpretation, nor even the interpretation deemed most reasonable by the courts." *Entergy Corp. v. Riverkeeper, Inc.*, 556 U.S. 208, 218 (2009).

Given the wide variety of administrative actions involving exercises of interpretive authority, *Chevron* does not apply automatically, even where an agency is interpreting a statute it administers. "To begin with, the [interpretation] must be promulgated pursuant to authority Congress has delegated to the official." *Gonzales v. Oregon*, 546 U.S. 243, 258 (2006) ("*Chevron* deference [ ] is not accorded merely because the statute is ambiguous and an administrative official is involved."). In other words, *Chevron* is the appropriate standard of review only "when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority." *United States v. Mead Corp.*, 533 U.S. 218, 226-27 (2001). This

forecloses *Chevron* deference in the context of § 340B, as "HHS has not been granted broad rulemaking authority to carry out all the provisions of the 340B program." *Pharm. Rsch.*, 43 F. Supp. 3d at 42. Congress instead has authorized HHS to issue rules in three limited contexts: to establish the ADR Rule, pursuant to which HHS has the authority to take six actions, 42 U.S.C. §§ 256b(d)(3)(A)-(B), to define standards and methodologies for calculating the ceiling price, *id.* § 256b(d)(1)(B)(i)(I), and to assess CMPs based on ADR proceedings. *Id.* § 256b(d)(1)(B)(vi)(I). These specific grants of authority do not warrant *Chevron* deference as to HHS' "entirely different" contract pharmacy interpretation. *Pharm. Rsch.*, 43 F.3d at 45. Neither, for that matter, do § 340B's tie-ins about enhancing program integrity expand HHS' interpretive or rulemaking authority to the point where the *Chevron* framework would apply. *City of Arlington*, 569 U.S. at 306 ("[F]or *Chevron* deference to apply, the agency must have received congressional authority to determine the particular matter at issue in the particular manner adopted."). HHS does not contend otherwise.

When *Chevron* does not apply, I turn to *Skidmore*. *See, e.g.*, *Mead*, 533 U.S. at 234-35 ("*Chevron* did nothing to eliminate *Skidmore*'s holding that an agency's interpretation may merit some deference whatever its form, given the specialized experience and broader investigations and information available to the agency . . . and given the value of uniformity in its administrative and judicial understandings of what a national law requires."); *Christensen v. Harris County*, 529 U.S. 576, 596 (2000) (Breyer, J., dissenting) ("[*Chevron*] simply focused upon an additional, separate reason for deferring to agency determinations, namely, that Congress had delegated to the agency the legal authority to make those determinations."). *Skidmore* instructs that an agency's "rulings, interpretations and opinions" may constitute "a body of experience and informed judgment to which courts and litigants may properly resort for guidance." *Mead*, 533 U.S. at 221; *Christensen*,

529 U.S. at 587. The appropriate level of deference due under *Skidmore* depends on whether an agency's interpretation has the "power to persuade," which in turn hinges on "the thoroughness evident in its consideration, the validity of its reasoning, [and] its consistency with earlier and later pronouncements." *Skidmore*, 323 U.S. at 140.

"Regardless of whether [I] apply *Chevron* or *Skidmore* deference, [the] initial inquiry requires [me] to determine whether [the relevant statute] is ambiguous" on the questions at issue. *Hagans v. Comm'r of Soc. Sec.*, 694 F.3d 287, 295 (3d Cir. 2012); *Catskill Mountains Chapter of Trout Unlimited, Inc. v. EPA*, 846 F.3d 492, 509 (2d Cir. 2017) (collecting cases). And if it is not, then as with *Chevron*, I do not defer. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 326 (2008) (suggesting that it is "unnecessary" to engage in *Skidmore* analysis if "the statute itself speaks clearly to the point at issue"); *Gen. Dynamics Land Sys., Inc. v. Cline*, 540 U.S. 581, 600 (2004) ("[D]eference to [an agency's] statutory interpretation is called for only when the devices of judicial construction have been tried and found to yield no clear sense of congressional intent."). I "conduct [the] ambiguity analysis as a matter of statutory interpretation," using the traditional canons of construction. *Hagans*, 694 F.3d at 295. Applying these principles, I turn to HHS' construction of § 340B.

ii. Contract Pharmacies in General Are Permissible Under § 340B

1. The 340B Statute Is Ambiguous on Contract Pharmacy Arrangements, Contrary to HHS' Position

In interpreting whether § 340B unambiguously permits contract pharmacy arrangements, I "begin with the text." *Vorchheimer v. Philadelphian Owners Ass'n*, 903 F.3d 100, 105 (3d Cir. 2018). Where it is clear, my inquiry "ends there as well." *Nat'l Ass'n of Mfrs. V. Dep't of Def.*, 138 S. Ct. 617, 631 (2018). In particular, I look to "the 'language itself, the specific context in which that language is used, and the broader context of the statute as a whole.'" *Blackman v.*

District of Columbia, 456 F.3d 167, 176 (D.C. Cir. 2006) (quoting *United States v. Barnes*, 295 F.3d 1354, 1359 (D.C. Cir. 2002)); *United States v. Tupone*, 442 F.3d 145, 151 (3d Cir. 2006) ("The Supreme Court has stated consistently that the text of a statute must be considered in the larger context or structure of the statute in which it is found."). The overarching goal is to effect Congress' intent. *Rosenberg v. XM Ventures*, 274 F.3d 137, 141 (3d Cir. 2001).

By its terms, § 340B is silent on what role (if any) contract pharmacies play in Congress' discount drug scheme. Pharmacies are not mentioned anywhere in it—neither in 42 U.S.C. § 256b(a)(1), which contains the "sum total of the statute's language regarding manufacturers' obligations," Novo Br., at 17, nor in § 256b(a)(4), which defines "covered entity." As the *AstraZeneca* Court observed with respect to the AO, "[w]hen a statute does not include even a single reference to the pertinent word (e.g., 'pharmacy'), it is highly unlikely (if not impossible) that the statute conveys a single, clear, unambiguous directive with respect to that word." 2021 WL 2458063, at *9. HHS has recognized as much, stating in its 1996 Guidance that § 340B "is silent as to permissible drug distribution systems" and contains "many gaps." 61 Fed. Reg. at 43,549.

HHS attempts to fill in these gaps by pointing to language in § 256b(a)(1), which provides that "the amount required to be paid . . . for outpatient drugs . . . *purchased by* a covered entity" cannot exceed the statutory ceiling price. *Id.* (emphasis added). HHS reads the "purchased by" provision to encompass all drugs a covered entity orders under the 340B Program, including those shipped directly to a contract pharmacy. HHS Opp., at 13. But § 256b(a)(1) cannot bear the weight HHS places on it. As the court in *AstraZeneca* noted, § 256b(a)(1) "imposes an obligation on the Secretary" to enter into PPAs with manufacturers, which is nothing more than the opt-in mechanism for the 340B Program, and contains no "reference to . . . the model by which the drugs

are distributed." 2021 WL 2458063, at *10. PPAs are otherwise standardized form contracts written by the Government. Section 256b(a)(1) thus adds nothing with respect to whether the statute on the whole permits contract pharmacy arrangements. *Accord Sun Wen Chen v. Att'y Gen. of U.S.*, 491 F.3d 100, 107 (3d Cir. 2007) ("Silence on a particular matter germane to the provisions of a statute suggests a gap of the sort that the administering agency may fill . . . [although] [a]n agency cannot read a statute discussing topic X to confer a power over unrelated topic Y just because the statute fails to mention topic Y.").

In determining whether § 340B unambiguously permits contract pharmacy arrangements, I must "presume that [Congress] says in a statute what it means and means in a statute what it says." *Conn. Nat'l Bank v. Germain*, 503 U.S. 249, 253-54 (1992). And Congress did not speak (through the text at least) in a way that yields any sense of what it intended.[50] *Gen. Dynamics*, 540 U.S. at 600. The 340B statute "contains no explicit reference to [contract pharmacies]." *Sun When Chen*, 491 F.3d at 107 (finding statute ambiguous at *Chevron*/*Skidmore* step one); *Arobelidze v. Holder*, 653 F.3d 513, 518-19 (7th Cir. 2011) ("When, as here, there are two plausible but different interpretations of statutory language, there is ambiguity."). For these reasons, while the Violation Letters are "not as explicit as the [AO]," San. Opp., at 21, they nonetheless make clear that HHS sees no ambiguity on the question whether Congress meant to permit contract pharmacies as a drug dispensing system—which is a mistaken legal interpretation.

---

50 The 340B Program also provides that "a covered entity shall not resell or otherwise transfer" drugs to any "person who is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(B). Plaintiffs—particularly Novo—claim this provision militates against HHS' position, to the extent that contract pharmacy arrangements can be characterized as transfers/resales to non-patients. Novo Br., at 18 (quoting *Altamont Gas Transmission Co. v. FERC*, 92 F.3d 1239, 1248 (D.C. Cir. 1996) (recognizing principle that agency may not "attempt[] to do indirectly what it could not do directly")). HHS has never interpreted § 256b(a)(5)(B) in this manner, and I agree that it is not a reasonable construction of the statute. The 340B Program's non-transfer/resale provision refers to situations where 340B drugs are given to individuals who are not receiving health care services from covered entities or are receiving services inconsistent with the type of services for which the covered entity qualified for 340B status.

Because § 340B contains no explicit grant of authority for covered entities to use contract pharmacies, yet HHS interpreted the statute as unambiguous on that point, the agency's position is not entitled to deference. *Fox v. Clinton*, 684 F.3d 67, 76 (D.C. Cir. 2012) (holding that an agency letter "obviously does not merit *Chevron* deference" and its persuasive power, "following *Skidmore*," is "virtually nil" because the relevant statute "is not . . . *unambiguous* on the matters in dispute," contrary to agency's claim) (emphasis in original); *Peter Pan Bus Lines, Inc. v. Fed. Motor Carrier Safety Admin.*, 471 F.3d 1350, 1354 (D.C. Cir. 2006) (declining to grant deference "when the agency wrongly 'believes that interpretation is compelled by Congress'") (quoting *PDK Laboratories, Inc. v. DEA*, 362 F.3d 786 (D.C. Cir. 2004)); *Prill v. NLRB*, 755 F.2d 941, 942, 948, 956 (D.C. Cir. 1985) (declaring regulation invalid, "even though the agency might be able to adopt the regulation in the exercise of its discretion, if it 'was not based on the agency's own judgment but rather on the unjustified assumption that it was Congress' judgment that such a regulation is desirable'"); *Am. Lung Ass'n v. Env't Prot. Agency*, 985 F.3d 914, 944 (D.C. Cir. 2021) (holding that an agency cannot base an interpretation "on an erroneous view of the law"); *Braintree Elec. Light Dep't v. FERC*, 667 F.3d 1284, 1288-89 (D.C. Cir. 2012) (Garland, J.) ("As long as the text is ambiguous and the agency does not insist that it is clear, a reasonable interpretation will warrant [some] deference."); *Hagans*, 694 F.3d at 304-05 (holding that "many of the same circumstances . . . relevant for determining whether to apply *Chevron* deference are also useful for deciding the level of deference due under *Skidmore*").

2. Contract Pharmacies Are Nevertheless Consistent with the 340B Statute

The fact that the 340B statute is ambiguous on contract pharmacies, and that HHS is not entitled to any agency deference, does not end the inquiry. It means only that I then determine whether the 340B statute permits contract pharmacies "the old-fashioned way," *Miller v. Clinton*,

687 F.3d 1332, 1342 (D.C. Cir. 2012), by deciding "for [myself] the best reading." *Landmark Legal Found. v. IRS*, 267 F.3d 1132, 1136 (D.C. Cir. 2001); *De Leon-Ochoa*, 622 F.3d at 350-51 (applying *de novo* review in a similar circumstance). In my view, HHS' position that the 340B statute does not wholly foreclose contract pharmacy arrangements, meaning that HHS has the statutory authority to require manufacturers to ship 340B drugs to at least one contract pharmacy site each, squares better with Congressional intent than Plaintiffs' position that Congress simply never intended to authorize such a dispensing mechanism.

I start with the legislative history, which weighs in favor of HHS. As a rule, I will not "resort to legislative history to cloud a statutory text that is clear." *Ratzlaf v. United States*, 510 U.S. 135, 147-48 (1994). However, "clear evidence of congressional intent may illuminate an ambiguous text," as with § 340B. *Milner v. Dep't of the Navy*, 562 U.S. 562, 572 (2011). Most significantly, in 1992, Congress removed language limiting 42 U.S.C. § 256b(a)(1) to drugs "purchased by *and dispensed by, or under a contract entered into for on-site pharmacy services with*," a covered entity. S. Rep. No. 102-259, at 2 (1992). The final statute refers only to drugs "purchased by" covered entities, without limiting (or remarking on) the dispensing mechanism. Presumably, had Congress retained the original language in § 256b(a)(1), the 340B Program would have excluded all off-site pharmacies from its drug discount scheme. Because Congress *eliminated* a clear limitation on contract pharmacy arrangements in the drafting process, it likely did not intend *to prohibit* them altogether.[51] *See, e.g.*, *Jama v. ICE*, 543 U.S. 335, 341 (2005) ("We do not lightly

51 The court in *AstraZeneca* found the legislative history to be "of no greater assistance to the government" than to the manufacturers. 2021 WL 2458063, at *10. While Plaintiffs use this to argue that the legislative history favors them, the *AstraZeneca* Court's observation must be read in the context of its conclusion that the statute does not speak clearly one way or the other and that both parties' interpretations are plausible. On the other hand, the *Eli Lilly* Court concluded, "[t]he fact that Congress once considered but rejected restricting covered entities' choice of dispensing mechanism in a manner consistent with Plaintiffs' position supports our statutory interpretation." 2021 WL 5039566, at *20 n.15.

assume that Congress has omitted from its adopted text requirements that it nonetheless intends to apply."); *Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 452 (2002) ("[I]t is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.") (quotations and citation omitted); *Russello v. United States*, 464 U.S. 16, 23 (1983) ("The evolution of these statutory provisions supplies further evidence that Congress intended § 1963(a)(1) to extend beyond an interest in an enterprise."); *Motion Picture Ass'n of Am., Inc. v. FCC*, 309 F.3d 796, 806 (D.C. Cir. 2002) ("After originally entertaining the possibility of providing the FCC with authority to adopt video description rules, Congress declined to do so. This silence surely cannot be read as ambiguity."); *Baker v. Bell Textron, Inc.*, No. 20-292, 2020 WL 5513431, at *4 (N.D. Tex. Sept. 14, 2020) ("The Court will not add requirements to the law that Congress could have included but did not."). Still more, in its Conference Committee Report, Congress stated that HHS is not authorized to limit the volume of drug purchases made by covered entities, which supports the agency's interpretation to the extent that a ban on contract pharmacy arrangements *per se* would entail a large-scale reduction in 340B sales.[52] H.R. Rep. No. 102-384, pt. 2, at 16 (1992).

---

52 The Administrative Record compiled by HHS contains aggregate price statistics which support this conclusion. AR, at 7,936-47. Prior to any restrictions, manufacturers—including Sanofi and Novo—sold 10.5 million 340B-priced units per month. Subsequent to their policies aimed at curbing contract pharmacy arrangements, they sold 2.9 million units. "Annualized this equates to a reduction in 340B units sold of nearly 83 [million]." *Id.* In October 2020, when Sanofi and two other manufacturers first imposed their restrictions, 340B sales shrunk from 9.4 million units to 5.1 million units, while sale of wholesale acquisition units more than doubled. Monthly 340B savings in turn fell from $357 million in July 2020 to $92 million in January 2021, representing annualized losses of $3.2 billion. In January 2021, alone, covered entities lost an estimated $234 million in savings, and an estimated $665 million in the four months prior. *Id.* Sanofi's 340B sales in particular dropped from 2.04 million units to .28 million units in the *month* after its initiative, while sales for its wholesale acquisition units rose from negligible to .37 million units. *Id.* at 7,937. Monthly 340B savings for Sanofi's customers totaled $54.2 million before the Integrity Initiative, but just $5 million two months after it. *Id.* at 7,939. By January 2021, covered entities lost an average of $43.4 million monthly to Sanofi's Integrity Initiative. *Id.* at 7,941. Likewise, Novo's 340B sales fell from 3.32 million to 1.19 million in one month, *id.* at 7,937; covered entities lost nearly $100 million in monthly savings (from $144.6 million to $47 million) to Novo's policy, *id.* at 7,939; average annual lost savings totaled $63 million per covered entity, *id.* at 7,941; and sales at the commercial rate jumped from negligible to .41 million. *Id.* at 7,937.

To adopt Plaintiffs' construction despite this legislative history would be to "narrow [§ 340B's] reach by inserting words Congress chose to omit." *Lomax v. Ortiz-Marquez*, 140 S. Ct. 1721, 1725 (2020).

Section 340B's declaration of purpose also favors HHS. In construing a statute, I may look not just to its plain language, but to the "object and policy" behind it as well as its "core objectives." *Dada v. Mukasey*, 554 U.S. 1, 16 (2008); *Brown & Williamson*, 529 U.S. at 133 ("Viewing the FDCA as a whole, it is evident that one of the Act's core objectives is to ensure that any product regulated by the FDA is 'safe' and 'effective' for its intended use."); *Freeman v. Quicken Loans, Inc.*, 566 U.S. 624, 632 (2012) (rejecting an interpretation of a statute that would undermine its purpose by imposing liability on "the very class for whose benefit [the statute] was enacted"). The Supreme Court routinely relies on purpose to "divine the meaning" of ambiguous statutes. *Gundy v. United States*, 139 S. Ct. 2116, 2126 (2019) (collecting cases); *Maracich v. Spears*, 570 U.S. 48, 76 (2013); *United Sav. Assn. of Tex. v. Timbers of Inwood Forest Associates, Ltd.*, 484 U.S. 365, 371 (1988) (understanding statutory interpretation as a "holistic endeavor").

The 340B Program is designed to "enable [covered] entities to stretch scarce Federal resources as far as possible," maximize the number of patients in low-income and rural areas, and pass on drug discounts to medically disadvantaged populations. H.R. Rep. No. 102-384, pt. 2, at 12 (1992). "On their face, of course, none of these statutorily identified purposes has anything to say about the precise question at issue—the use of [contract pharmacies as a dispensing mechanism]." *Pension Benefit Guaranty Corp. v. LTV Corp.*, 496 U.S. 633, 649 (1990). Yet, where the "*logical consequence*" of an interpretation is inconsistent with the goals of a statute, that "provides strong indication that something in [the] interpretation is amiss." *Freeman*, 566 U.S. at 632 (emphasis in original). Section 340B is aimed at benefiting small, often remote, and almost

always resource-limited providers who are receiving federal assistance for serving disadvantaged populations. Most of these providers could not afford to meaningfully participate in the 340B Program on their own, if at all.[53] 42 U.S.C. § 256b(a)(4) (defining covered entities). Contract pharmacy arrangements are not just commonplace, then, but they are a necessary—perhaps even indispensable—means of attaining § 340B's ends. They enable safety net providers to expand their distribution networks for 340B drugs, fill more prescriptions, and generate additional savings and revenue to fund both higher discounts and more comprehensive healthcare services. Plaintiffs' interpretation, on the other hand, would dramatically scale back § 340B.

In much the same way and for much the same reasons, "the presumption against ineffectiveness" supports HHS' reading of the 340B statute. *United States v. Castleman*, 572 U.S. 157, 178 (2014) (Scalia, J., concurring in part). Under the presumption, "a textually permissible interpretation that furthers rather than obstructs [a statute's] purpose should be favored" over one that does not. *Tex. Workforce Comm'n v. U.S. Dep't of Educ.*, 973 F.3d 383, 389 (5th Cir. 2020) (citation omitted). Absent contract pharmacy arrangements, § 340B may be "a dead letter in" many of its applications "from the very moment of its enactment," given the number of covered entities which cannot afford to create or maintain in-house pharmacies. *United States v. Hayes*, 555 U.S. 415, 427 (2009) (quotations and citation omitted).

53 Indeed, covered entities without in-house pharmacies cannot easily set them up. To do so requires state licensing, registration with the Drug Enforcement Agency ("DEA"), employing persons legally able to dispense drugs, establishing appropriate storage space and protocols to safeguard medications, purchasing software to bill insurers, and other cost-prohibitive actions. Unsurprisingly, the majority of covered entities do not operate a licensed pharmacy or even employ a pharmacist—and thus are not in a position to handle their own dispensing or take delivery of 340B drugs. Were it as burdenless as Plaintiffs insist for covered entities to participate in the 340B Program through in-house pharmacy services, then 340B sales would not have dropped so precipitously as soon as Plaintiffs implemented their policies curbing contract pharmacy deliveries. *See supra*, note 52.

Third, based on § 340B's post-enactment history, Congress has seemingly ratified contract pharmacy arrangements. The Supreme Court has "recognized congressional acquiescence to administrative interpretations of a statute in some situations," *Solid Waste Agency of N. Cook Cty. v. U.S. Army Corps of Engineers*, 531 U.S. 159, 169 (2001), such as "where there is evidence that Congress considered and rejected the "precise issue" now before the court, *Bob Jones Univ. v. United States*, 461 U.S. 574, 600 (1983), or the agency's "interpretation [is] discernible and longstanding." *CASA de Maryland, Inc. v. Trump*, 971 F.3d 220, 247 (4th Cir. 2020). In other words, "[i]t is well established that when Congress revisits a statute giving rise to a longstanding administrative interpretation without pertinent change, the 'congressional failure to revise or repeal the agency's interpretation is persuasive evidence that the interpretation is the one intended by Congress.'" *Schor*, 478 U.S. at 846 (quoting *NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 274-75 (1974)); *FDIC v. Philadelphia Gear Corp.*, 476 U.S. 426 (1986).

Congress last expanded § 340B in 2010, both to add new covered entities and to adjust Medicaid eligibility criteria to include certain nonprofit hospitals. When doing so, it is reasonable to presume that Congress knew about the well-settled 1996 Guidance permitting at least one contract pharmacy per covered entity, yet it did not revise the 340B statute to chart a different course. "This failure to change the scheme under which [HHS] operated is significant." *Young v. Cmty. Nutrition Inst.*, 476 U.S. 974, 983 (1986). As well, Congress expanded § 340B in 2003, in the Medicare Modernization Act, causing the number of hospitals serving certain low-income patients to jump by 600, without addressing HHS' policy in the 1996 Guidance. "These circumstances provide further evidence—if more is needed—that Congress intended the [a]gency's interpretation, or at least understood the interpretation as statutorily permissible." *Barhart v. Walton*, 535 U.S. 212, 220 (2002); *Schor*, 478 U.S. at 845-46 ("Such deference is

especially warranted here, for Congress has twice amended the CEA . . . but has not overruled the CFTC's assertion of jurisdiction.").

Fourth, the overall statutory scheme tends to support HHS' reading of § 340B. As mentioned earlier, "statutory interpretation turns on the language itself, the specific context in which that language is used, and the broader context of the statute as a whole." *Nken v. Holder*, 556 U.S. 418, 426 (2009) (quotations and citation omitted); *City of Rancho Palos Verdes v. Abrams*, 544 U.S. 113, 127 (2005) (Breyer, J., concurring) ("[C]ontext, not just literal text, will often lead a court to Congress' intent in respect to a particular statute."). This is "a fundamental canon of statutory construction." *Nat'l Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 666 (2007) (quotations omitted); *Utility Air Regulatory Group v. EPA*, 573 U.S. 302, 321 (2014). The Supreme Court has construed statutes in this manner since the founding. *See, e.g.*, *Pennington v. Coxe*, 6 U.S. 33, 52-53 (1804) ("That a law is the best expositor of itself, that every part of an act is to be taken into view, for the purpose of discovering the mind of the legislature; and that the details of one part may contain regulations restricting the extent of general expressions used in another part of the same act, are among those plain rules laid down by common sense for the exposition of statutes which have been uniformly acknowledged."). Relying on "the context and structure of the act," the Court has gone so far as to "depart from what would otherwise be the most natural reading of [a] pertinent statutory phrase" because "[i]t is implausible that Congress meant the Act to operate" that way. *King v. Burwell*, 576 U.S. 473, 476 (2015).

Here, just 500 of 11,000 covered entities maintained in-house pharmacies when Congress passed § 340B in 1992. 61 Fed. Reg. at 43,550. It is unrealistic to assume that "Congress enacted a comprehensive legislative scheme to aid safety-net providers and vulnerable patients—but intentionally and implicitly structured it in such a way that only 5% of the providers statutorily

eligible to participate would be able to access the program in practice." U.S. Opp., at 21. While recognizing this point, Plaintiffs suggest that other statutory provisions cut against it. For instance, another provision in the VHCA refers to "drugs procured by an agency of the Federal Government" and "received[,] stored, and delivered" by "a commercial entity operating under contract with such agency." 38 U.S.C. § 8126(h)(3). And at least one other federal healthcare statute references "a person authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services reimbursed under a Federal health care program." 42 U.S.C. § 1320a-7b(3)(C). From these, Plaintiffs infer that Congress knows how to write statutes covering contract-like arrangements, but deliberately did not do so in § 340B.

Rarely, however, do courts draw a negative inference about Congressional intent across different phrasings in different statutes drafted at different times on different subject matter, as with § 340B and § 1320a-7b(3)(C). *Gross v. FBL Fin. Servs.*, 557 U.S. 167, 174 (2009) ("When conducting statutory interpretation, [a court] must be careful not to apply rules applicable under one statute to a different statute without careful and critical examination.") (quoting *Fed. Express Corp. v. Holowecki*, 552 U.S. 389, 393 (2008)); *Hardt v. Reliance Std. Life Ins. Co.*, 560 U.S. 242, 253-54 (2010) (holding that construction of statute referring to "prevailing party" was not governed by "[o]ur 'prevailing party' precedent" because statute at issue contained different terms); *FAA v. Cooper*, 566 U.S. 284, 292-293 (2012) ("actual damages" has different meanings in different statutes); *United States v. Bankoff*, 613 F.3d 358, 367 (3d Cir. 2010) ("[T]hat Congress used different language to incorporate § 1114 in different statutes that were codified nearly four decades apart . . . does not, standing alone, demonstrate that it used the term 'official' (as opposed to 'person') in § 115 with the intention of limiting its scope.").

In fact, the Supreme Court has "several times affirmed that *identical* language may convey varying content when used in different statutes, sometimes even in different provisions of the *same* statute." *Yates v. United States*, 574 U.S. 528, 537-38 (2015) ("[T]he same words, placed in different contexts, sometimes mean different things.") (emphasis added); *Wachovia Bank, N.A. v. Schmidt*, 546 U.S. 303, 313-14 (2006) ("located" has different meanings in different provisions of the National Bank Act); *General Dynamics*, 540 U.S. at 595-97 ("age" has different meanings in different provisions of the Age Discrimination in Employment Act of 1967); *United States v. Cleveland Indians Baseball Co.*, 532 U.S. 200, 213 (2001) ("wages paid" has different meanings in different provisions of Title 26); *Robinson v. Shell Oil Co.*, 519 U.S. 337, 343-44 (1997) (employee" has different meanings in different sections of Title VII of the Civil Rights Act of 1964); *Merrell Dow Pharmaceuticals Inc. v. Thompson*, 478 U.S. 804, 807-08 (1986) ("arising under" has different meanings in U.S. Const. art. III, § 2, and 28 U.S.C. § 1331); *District of Columbia v. Carter*, 409 U.S. 418, 420-21 (1973) ("State or Territory" has different meanings in 42 U.S.C. § 1982 and § 1983); *Atlantic Cleaners & Dyers, Inc. v. United States*, 286 U.S. 427, 433-37 (1932) ("trade or commerce" has different meanings in different sections of the Sherman Act).

Sometimes, of course, the Supreme Court will permit a negative inference "from the exclusion of language of one statutory provision that is included in other provisions of the same statute." *Hamden v. Rumsfeld*, 548 U.S. 557, 578 (2006); *Bailey v. United States*, 516 U.S. 137, 146 (1995). "[N]egative implications raised by disparate provisions are strongest when the portions of a statute treated differently had already been joined together and were being considered simultaneously when the language raising the implication was inserted." *Lindh v. Murphy*, 521 U.S. 320, 330 (1997); *Martin v. Hadix*, 527 U.S. 343, 356 (1999). Still, "[t]he force of any negative

implication depends on context." *Marx v. Gen. Revenue Corp.*, 568 U.S. 371, 381 (2013) (noting that the canon of *expression unius est exclusion alterius* can be overcome by "contrary indications that adopting a particular rule or statute was probably not meant to signal any exclusion") (citation omitted). For "words are chameleons, which reflect the color of their environment." *Commissioner v. Nat'l Carbide Corp.*, 167 F.2d 304, 306 (2d Cir. 1948) (Hand, J.). Sections 340B and 8126(h)(3) appear to have sufficiently different contexts and purposes to warrant different meanings, despite their shared enactment history. Section 8126(h)(3) establishes discount rates for certain drugs acquired by HHS, the Department of Defense, the Public Health Service, the Indian Health Service, and the Coast Guard. Because the statute also governs drug maintenance and disposition, it uses the term "depot," defined as a "centralized commodity management system through which" drugs are "received, stored, and delivered." *Id.* § 8126(h)(3)(A). A depot may include a "federally owned and operated warehouse system" or "a commercial entity operating under contract" for the same. *Id.* § 8126(h)(3)(A)(i)-(ii). Section 340B, on the other hand, governs drug sales between private entities, and contract pharmacies arise as a one-of-a-kind dispensing mechanism. *Atlantic Cleaners & Dryers*, 286 U.S. at 433 ("Where the subject matter to which the words refer is not the same in the several places where [the words] are used, or the conditions are different, or the scope of the legislative power exercised in one case is broader than that exercised in another, the meaning well may vary to meet the purposes of the law.").

Finally, the Supreme Court has suggested that certain issues are of such "extraordinary" significance that courts should seek a clear statement from Congress (in the statute) before concluding that an agency has the authority to act, particularly when a provision is ambiguous. *King*, 576 U.S. at 485-86 (ACA subsidies); *Gonzales*, 546 U.S. at 266-67 (assisted suicide); *Brown & Williamson*, 529 U.S. at 159 (tobacco regulation); *Utility Air Regulatory Group*, 573 U.S. at 324

(greenhouse gas emissions); *MCI Telecomm'ns Corp. v. AT&T Co.*, 512 U.S. 218, 228 (1994) (rate regulation). This is the so-called major questions doctrine, and it is applicable where there are "special reasons for doubt" about whether Congress intended to grant authority to an agency, such as serious political or economic ramifications, or where it is "implausible in light of the statute and subject matter in question that Congress authorized such unusual agency action." *Am. Lung Ass'n*, 985 F.3d at 959. The Supreme Court recently relied on it in *Alabama Ass'n of Realtors v. Dep't of Health and Human Servs.*, 141 S. Ct. 2485 (2021) (per curiam), to strike down the Center for Disease Control's ("CDC") eviction moratorium. *Id.* at 2489. Novo raises it here because "the policy repercussions of forcing manufacturers to allow commercial pharmacies to participate in, and profit off of, the 340B Program are so significant that there is no reason to think that Congress would have delegated that decision to agency officials" without more clarity. Novo Br., at 2, 21.

But this matter neither implicates the concerns underlying the major questions doctrine nor fits the pattern of cases in which the Supreme Court has invoked it. Unlike *Brown & Williamson*, HHS has had regulatory authority over the 340B Program generally—and contract pharmacy arrangements specifically—for thirty years, and it is the agency Congress intended (by statute) to effectuate § 340B. Novo expressly concedes that HHS' ability to require it to ship drugs to one contract pharmacy per covered entity is lawful, and it seeks a return to that era of the Program. By contrast, in *Brown & Williamson*, the FDA asserted jurisdiction over tobacco products after nearly 80 years of not doing so, and despite representations to Congress that it never could. 529 U.S. at 159-60. In addition, it makes sense for Congress to house authority over contract pharmacy arrangements in HHS, which has substantial expertise in crafting healthcare policy, and HRSA, which administers programs for medically vulnerable populations. Contrast these facts with *King*, where the Supreme Court doubted whether Congress would have delegated billions of dollars in

health insurance subsidies for millions of people to the IRS, a tax agency. 576 U.S. at 486. Likewise, in *Gonzales*, the Court found it unlikely that Congress would have delegated medical judgments to the Attorney General, "an executive official who lacks [such] expertise." 546 U.S. at 265-267. And unlike *Alabama Ass'n of Realtors*, where the CDC claimed "breathtaking" authority over "at least 80% of the country, including between 6 and 17 million tenants at risk of eviction," at a cost of approximately $50 billion, the 340B Program constitutes a fraction of the overall prescription drug market (about 5%) and a larger but still relatively small percentage of the branded drug market (about 14%), even if it is the second largest federal drug purchasing program. 141 S. Ct. at 2480. Accordingly, I do not find that these circumstances warrant application of the major questions doctrine.

My conclusion that contract pharmacy arrangements as a dispensing mechanism are consistent with § 340B notably comports with Plaintiffs' own policies, both of which permit at least one contract pharmacy per covered entity. Novo goes so far as to say that interpretation is permissible, while Sanofi (as well as all other participating manufacturers) have never objected to it. The key difference is this: while Plaintiffs insist that they could write different policies at any time and HHS' hands would be tied in response, I find that HHS has the statutory authority to *require* shipment to at least one contract pharmacy per covered entity, regardless of what Plaintiffs' policies say on the subject.

Accordingly, reading the 340B statute "as a whole," *United States v. Atl. Research Corp.*, 551 U.S. 128, 135 (2007), and focusing on "the relevant words not in a vacuum, but with reference to the statutory context, structure, history, and purpose," contract pharmacy arrangements are permissible as a drug dispensing mechanism. *Abramski v. United States*, 573 U.S. 169, 179 (2014) (citations omitted); *Textron Lycoming Reciprocating Engine Div. Avco Corp. v. United Auto.,*

Aerospace & Agric. Implement Workers of Am., 523 U.S. 653, 657 (1998) (same); *Regions Hosp. v. Shalala*, 522 U.S. 448, 460 n.5 (1998) (same). To the extent that the Violation Letters depend on or advance that interpretation of § 340B, they do not exceed statutory authority nor are they contrary to law.

Additionally, in the end, Plaintiffs' position in this litigation is unpersuasive because "[a]n inference drawn from congressional silence certainly cannot be credited when it is contrary to all other textual and contextual evidence of congressional intent," *Burns v. United States*, 501 U.S. 129, 136 (1991), and because "[t]he mere possibility of clearer phrasing cannot defeat the most natural reading of [the] statute." *Caraco Pharm. Labs. v. Novo Nordisk A/S*, 566 U.S. 399, 416 (2012). As is usual in these cases, Plaintiffs' recourse lies more properly with Congress. *United States v. Thirty-seven (37) Photographers*, 402 U.S. 363, 369 (1971) (explaining that "it is for Congress, not this Court, to rewrite [a] statute"); *Hartford Underwriters Ins. Co. v. Union Planters Bank, N.A.*, 530 U.S. 1, 13-14 (2000) ("Achieving a better policy outcome . . . is a task for Congress, not the courts."); *TVA v. Hill*, 437 U.S. 153, 185 (1978) ("It is not for us to speculate, much less act, on whether Congress would have altered its stance had the specific events of this case been anticipated."); *Bostock v. Clayton County*, 140 S. Ct. 1731, 1753 (2020) (interpreting a "starkly broad statute" to have many "unexpected applications").

iii. Plaintiffs' Policies Are Impermissible Under § 340B

I next turn to Plaintiffs' policies, which prohibit covered entities from using multiple contract pharmacies unless they comply with certain conditions. In Sanofi's case, the condition is claims-level data reporting, whereas in Novo's case, it is a sufficiently low risk of fraud or abuse (as determined by Novo, based on unspecified criteria). Plaintiffs argue that, because the 340B statute does not impose any express obligations on manufacturers besides the drug discount rate,

they are free to attach whatever strings they deem necessary to 340B sales. Plaintiffs rest their entire theory on statutory language providing that a manufacturer "*shall offer* each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price." 42 U.S.C. § 256b(a)(1) (emphasis added). They read the "shall offer" provision to mean that "[n]othing . . . prevents [them] from imposing [ ] condition[s]" on 340B offers, as long they comply with the statutory ceiling price. San. Opp., at 15. I disagree.

For one thing, Plaintiffs take the "shall offer" provision far afield of its context. Passed in 2010, it mostly reiterates that manufacturers cannot prioritize full-priced commercial purchases over § 340B sales, which is a separate and distinct requirement of the 340B Program. 82 Fed. Reg. at 1,225. It has little bearing on the question whether, or to what extent, Plaintiffs can attach strings to 340B sales. Beyond that, Plaintiffs do not point to anything in the statutory text, or outside of it, indicating that Congress *omitted* language on offer conditions because it *actually intended* to delegate discretion to manufacturers to impose them.

This leaves Plaintiffs with no basis for their reading of the statute, except that HHS "fails to identify any statutory text *prohibiting* [their policies]." San. Opp., at 15 (some alterations in original). But authority for Plaintiffs' policies does not follow from the statutory silence and is not implicitly included in § 340B. First, as Plaintiffs admit, "Congress . . . does not hide elephants in mouseholes." *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001). Congress will not, in other words, "alter the fundamental details of regulatory schemes in vague terms or ancillary provisions." *Id.* Yet that is exactly what Plaintiffs propose doing here: in their view, I should locate a unilateral power to impose offer conditions in a provision Congress added to § 340B eighteen years after enacting the Program, and which Congress passed largely to ensure equal treatment between covered entities and commercial purchasers. Relatedly, there is no "such thing as a 'canon

of donut holes,' in which Congress's failure to speak directly to a specific case [offer conditions on contract pharmacy sales] that falls within a more general statutory rule [the "shall offer" provision] creates a tacit exception. Instead, when Congress chooses not to include any exceptions to a broad rule, courts apply the broad rule." *Bostock*, 140 S. Ct. at 1747. Congress' use of general language in the "shall offer" provision does not permit Plaintiffs to take specific actions, like their policies, just because those actions are not expressly prohibited by the broad text. Finally, Plaintiffs' policies would threaten to undo the statutory scheme by rendering 340B offers hollow, *United States v. Hayes*, 555 U.S. 415, 426-27 (2009) (declining to read a statute to "frustrate Congress' manifest purpose"), and "what Congress has plainly done . . . devoid of . . . effect." *Great-West Life & Annuity Ins. Co. v. Knudsen*, 534 U.S. 204, 217-18 (2002). For these reasons, the 340B statute forecloses Plaintiffs' policies. The *Eli Lilly* Court reached the same conclusion on similar grounds. 2021 WL 5039566, at *18, *20 n.15 ("Congress in no way intended to allow regulated entities to unilaterally erect barriers—such as Lilly's delivery restrictions—the effect of which frustrate the overarching purpose of the program based on a rationale that such restrictions are not explicitly prohibited by the plain language of the statute.").

This is not to question the seriousness of drug diversion and duplicate discounting, which § 340B prohibits and which are increasingly serious problems. It is simply to say that Plaintiffs' policies are an *ultra vires* way to remedy them. Further, according to Congress, concerns regarding duplicate discounting or diversion must be resolved through the ADR Rule. 42 U.S.C. § 256b(d)(3)(B)(iv). Plaintiffs may conduct audits, then file disputes should they surface evidence of waste or fraud. 42 U.S.C. § 256b(d)(3)(A). Or they may work in "good faith" with covered entities. 85 Fed. Reg. 80,633 (stating that the ADR Rule is "a last resort"). They may also negotiate with HHS. They may even lobby Congress. *Patriotic Veterans, Inc. v. Indiana*, 736 F.3d 1041,

1047 (7th Cir. 2013) ("If Congress determines later that the plain language of the statute does not accurately reflect the true intent of Congress, it is for Congress to amend the statute."). But Plaintiffs may not unilaterally create and establish policies—whatever the underlying rationale—wherein they dictate how many contract pharmacies a covered entity may designate to receive delivery of covered drugs.

iv. Whether § 340B Permits Multiple or Unlimited Contract Pharmacy Arrangements

One final and significant issue surrounds the Violation Letters, even if the Letters do not specifically address it, and thus bears discussion: whether HHS has the statutory authority to require Plaintiffs to ship their drugs to multiple or unlimited contract pharmacies. In other words, unresolved is how many contract pharmacies the 340B statute permits, if there is a ceiling at all. Rather than decide this issue, I remand to the agency for "additional investigation or explanation." *Negusie v. Holder*, 555 U.S. 511, 523 (2009); *Gonzales*, 547 U.S. at 186 ("[T]he proper course, except in rare circumstances, is to remand."); *INS v. Orlando Ventura*, 537 U.S. 12, 16-17 (2002) (per curiam) (describing the remand rule as "ordinary"). In turn, I partially vacate and remand the Letters[54] as follows: I uphold HHS' assessment that Plaintiffs cannot impose restrictions on offers to covered entities and that their policies must cease, but I vacate HHS' determination that Plaintiffs owe credits or refunds to covered entities, and face CMPs, to the extent that such

54 The *Eli Lilly* Court also declined to answer this question, although it vacated the letter there for a different reason. *See, e.g.*, 2021 WL 5039566, at *20 ("We repeat: we do not agree with Plaintiffs' premise that to uphold the agency's determination set forth in the May 17 Letter, we must interpret the 340B statute to require drug manufacturers to deliver to an unlimited number of contract pharmacies."); *id.* at *24 ("For the reasons detailed above, we have determined that, though the 340B statute does not unambiguously require drug manufacturers to deliver drugs to an unlimited number of contract pharmacies as the [AO] would require, the statute, correctly construed, does not permit drug manufacturers, such as Lilly, to impose unilateral extra-statutory restrictions on its offer to sell 340B drugs to covered entities utilizing multiple contract pharmacy arrangements.").

determinations may depend on the number of permissible contract pharmacy arrangements under the 340B statute.

The reason, I believe, is straightforward: HHS is in a better position (at least initially) to grapple with the policy choices and balance the competing statutory priorities. *Nat'l Cable & Telecommunications Ass'n v. Brand X Internet Services*, 545 U.S. 967, 980 (2005). In doing so, the agency "can bring its expertise to bear upon the matter; it can evaluate the evidence; it can make an initial determination; and . . . , through informed discussion and analysis, help a court later determine whether its decision exceeds the leeway that the law provides." *Gonzales*, 547 U.S. at 186-87 (citation omitted). For instance, § 340B specifically prohibits drug diversion and duplicate discounting. 42 U.S.C. §§ 256b(a)(5)(A)-(B). Yet, according to the GAO, contract pharmacy arrangements increase the rate of fraud in the 340B Program.[55] A limitless number of contract pharmacies (or perhaps even a lesser number) may render the *overall* statutory scheme unworkable, undermine how Congress intended *all* of § 340B's provisions to work together, or otherwise affect how HHS can lawfully exercise its enforcement authority—particularly since Congress entrusted HHS to curtail abuses. Similarly, HHS may need to assess, based on factual evidence and a record, whether it must treat every covered entity the same under the statute with respect to the permissible number of contract pharmacy arrangements, or whether it may devise different benchmarks for determining the appropriate number of contract pharmacy sites for a particular type of covered entity.[56] To demonstrate, providers in sparsely populated rural areas may

55 GAO Report, *supra*, note 19, at 37, 44 (noting that, in 2017, out of 380 total compliance audits, 249 found drug diversion at contract pharmacies, or 66% of all such incidents); *id.* at 44 (noting that "noncompliance at contract pharmacies raises questions about the effectiveness of covered entities' current oversight practices"); *id.* at 45 ("The expansion of contract pharmacies . . . increases potential risks to the 340B Program . . . related to diversion and duplicate discounts.").

56 Different types of covered entities rely on contract pharmacy arrangements to different extents. *Id.* at 16-18. Contract pharmacy characteristics also vary widely based on the type of covered entity. *Id.* at 16.

require more contract pharmacy sites spread further apart than providers in densely populated urban areas where there are fewer barriers to access, such as travel time or transportation costs, and where in-house pharmacies can reach a greater proportion of eligible patients. The point is that HHS is in the best position to assess how to group or categorize covered entities, if at all, develop guideposts for contract pharmacy use, if necessary, and weigh the tradeoffs.

To be sure, the 2010 Guidance offers reasons for construing the 340B statute to permit multiple contract pharmacy arrangements, concludes that covered entities have the tools necessary to manage diversion, and includes various "essential elements" for preventing fraud or abuse. *See, e.g.*, 75 Fed. Reg. at 10,273 ("The circumstances surrounding pharmacy practice and the resources available to track transactions have changed substantially over the past decade . . . [permitting] covered entities to utilize multiple contract pharmacies without sacrificing program integrity . . . . pharmacy and inventory management processes are available that make utilization of more than one pharmacy readily feasible for many covered entities without increasing the risk of diversion."); *id.* at 10,278 (describing essential elements). But there is no dispute that the 340B landscape (with respect to contract pharmacies) has changed dramatically since 2010, and with it, the nature of the risks.

Tens of thousands of contract pharmacy arrangements exist now,[57] and covered entities have "weak" oversight measures which "impede" their ability to "ensure compliance."[58] Covered entities often maintain idle contract pharmacy agreements because doing so may be "financially

57 93 percent of these are community/retail pharmacies, and 75 percent are chains, or pharmacies with four or more locations under common ownership. *Id.* at 20-21 & n.35. Walgreens in particular accounts for 31 percent of all contract pharmacies nationwide. *Id.* at 21 n.36.

58 *Id.* at 45 (suggesting that the steps covered entities have taken in recent years may not be enough).

beneficial in the future."[59] Retail chains like CVS or Walgreens, which have sprung up in large number since 2010, may use the 340B Program for profit,[60] in particular by declining to pass along drug discounts (defined as a price below the wholesale acquisition cost) to covered patients.[61] And some covered entities never possess the 340B drugs they order under the replenishment model,[62] which Plaintiffs assert is inherently diversionary, while other covered entities use more standard models, which Plaintiffs do not dispute. All to say, there may be a point at which the number of contract pharmacy arrangements ceases to advance Program goals, such as making drugs as cheap as possible for underinsured communities, undermines Congress' other statutory priorities, such as preventing fraud and abuse, or squares better with the needs and characteristics of certain covered entities over others. HHS must therefore undertake a more complete assessment of the status quo *as to contract pharmacy arrangements* to determine whether it is permissible under the 340B statute to enforce a one-size-fits-all contract pharmacy policy, or whether more specific and holistic guidance is necessary.

My decision to partially vacate and remand the Letters reflects the sentiment, expressed in *Eli Lilly*, that courts "do not presume to have a full, integrated understanding of the way(s) in

---

59 *Id.* at 18.

60 Contract pharmacies are paid a flat fee "generally ranging" from $6 to $15 for each 340B prescription they dispense. *Id.* at 26. Neither the 340B statute nor agency guidance imposes a limitation on fee amount. *Id.* at 13 n.26. The lowest fee was $0 for some generic drugs, while the highest was $1,750 for a hepatitis C medication. *Id.* at 26 n.36.

61 *Id.* at 30 ("Of the 55 covered entities responding to our questionnaire, 30 reported providing low-income, uninsured patients discounts on 340B drugs dispensed at some or all of their contract pharmacies, and 25 said they did not offer discounts at their contract pharmacies.").

62 Under the replenishment model, a dispensing pharmacy such as Walgreens or CVS treats all drugs it receives (from whatever manufacturer) as neutral inventory. When it fills an order for a patient, it does not know (at that moment) whether a covered entity wrote the prescription. 340B eligibility is later determined by a software program, at which point the pharmacy may place a "replenishment order" with its covered entity partners for any drugs dispensed pursuant to § 340B.

which the 340B program should properly and fairly be administered going forward in a way that attempts to reflect the dramatically altered healthcare landscape in which the regulated parties now operate." 2021 WL 5039566, at *24. Likewise, my decision takes care "not to extend the scope of the statute beyond the point where Congress indicated it would stop." *United States v. Article of Drug . . . Bacto-Unidiski*, 394 U.S. 593, 600 (1951). Obviously, however, many of the outstanding issues in this case would be best addressed were Congress to step in and expressly state its intentions for the direction of the 340B statute, as well as HHS' role in administering it. For, like the *Eli Lilly* Court, I "cannot divine whether Congress intended for drug manufacturers to have unlimited delivery obligations under the statute, untethered to the particular covered entity's actual distribution needs." 2021 WL 5039566, at *24.

v. HHS' Interpretation of "Overcharge" Is Consistent with the 340B Statute

Finally, and in any event, HHS did not erroneously interpret the statutory term "overcharge" in the Violation Letters. In addressing this issue, I must "giv[e] the words used their ordinary meaning." *Lawson v. FMR LLC*, 571 U.S. 429, 440 (2014). An overcharge, by definition, means "to charge too much" compared to the value of a product.[63] *Yates*, 574 U.S. at 537 ("Ordinarily, a word's usage accords with its dictionary definition."). It is immaterial *to the fact of the overcharge* how, exactly, it was assessed. The 340B statute contains no language replacing or modifying this meaning. *Sebelius v. Cloer*, 569 U.S. 369, 376 (2013) ("[U]nless otherwise defined, statutory terms are generally interpreted in accordance with their ordinary meaning."); *BP Am. Prod. Co. v. Burton*, 549 U.S. 84, 91 (2006) (same). Rather, the statute is explicit: it provides that a manufacturer faces a CMP whenever it "charges a covered entity a price for purchase of a drug that exceeds the statutory maximum." 42 U.S.C. § 256b(d)(1)(B)(vi)(III). Read in this light,

63 Merriam-Webster, Overcharge, *available at* www.merriam-webster.com/dictionary/overcharge (last visited Nov. 4, 2021).

purchase orders that are denied due to an *ultra vires* eligibility restriction "result in" a covered entity "paying more than" the "ceiling price" to the same extent as misprices "under" the 340B Program, assuming that the covered entity buys the drugs at the wholesale acquisition or commercial rate. In turn, it is reasonable for HHS to conclude that Plaintiffs' policies constitute overcharges in the sense of § 340B.

Plaintiffs resist this straightforward conclusion. They would instead "have [me] read an absent word into the statute," *Lamie v. United States Trustee*, 540 U.S. 526, 538 (2004), resulting "not [in] a construction of [the] statute, but, in effect, a[] [narrowing] of it by the court, so that what was omitted [ ] . . . may be included." *Iselin v. United States*, 270 U.S. 245, 251 (1926) ("To supply omissions transcends the judicial function."); *Lawson*, 571 U.S. at 440 ("FMR's interpretation of the text requires the insertion of 'of a public company' after 'an employee' . . . . nothing in [the statutory] language confines the class of employees protected [in this manner]."). "With a plain, nonabsurd meaning in view, [I] need not proceed in this way." *Lamie*, 540 U.S. at 548. That is, I need not "soften the import" of Congress' "chosen word[]" by borrowing Plaintiffs' narrower construction absent any evidence that Congress intended me to do so. *Id.*; *Nichols v. United States*, 136 S. Ct. 1113, 1118 (2016) (citation omitted). If more evidence is needed, I find it implausible that Congress meant to ban a less egregious type of overcharge (a calculation error resulting in a 340B misprice), while permitting a more egregious type (an eligibility restriction resulting in a denial of a 340B discount altogether). If in fact Congress "intended [such a] bizarre result," *Caron v. United States*, 524 U.S. 308, 315 (1998), "surely it would have expressed [as much] in straightforward English." *FMC Corp. v. Holliday*, 498 U.S. 52, 66 (1990) (Stevens, J., dissenting).

vi. The Violation Letters Do Not Contravene the Takings Clause

In a last-ditch attempt to invalidate the Violation Letters, Novo (but not Sanofi) asserts that they effect a taking of private property for the sole benefit of contract pharmacies and impose an unconstitutional condition on a valuable government benefit: access to Medicaid/Medicare. Novo Br., at 29. Although Novo advances little substantive argument on this issue, I address it in full for the sake of clarity and completeness. The Supreme Court has distinguished between two kinds of takings: physical and regulatory. *Tahoe-Sierra Pres. Council, Inc. v. Tahoe Reg'l Planning Agency*, 535 U.S. 302 (2002); *Yee v. City of Escondido*, 503 U.S. 519, 522 (1992) (same). A physical taking occurs when there is a condemnation, appropriation, or occupation of property—to whatever extent, and regardless of whether the property is personal or real. *Tahoe-Sierra,* 535 U.S. at 302 (establishing rule); *Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063, 2071 (2021) (collecting examples); *Horne v. Dep't of Agriculture*, 576 U.S. 350, 364 (2015) (applying it to personal property). In such cases, the government must "pay for what it takes." *Cedar Point*, 141 S. Ct. at 2072.

A regulatory taking occurs when some significant restriction is placed upon an owner's use of its property. *Goldblatt v. Hempstead*, 369 U.S. 590, 594 (1962). That is, when a regulation "goes too far." *Penn. Coal Co. v. Mahon*, 260 U.S. 393, 415 (1922). There are two distinct tests in this context. *Nekrilov v. City of Jersey City*, No. 19-22182, 2021 WL 1138360, at *6 (D.N.J. Mar. 24, 2021). One is the "per se" test, which provides that a regulation is a taking if it destroys "all economically beneficial or productive" uses of the property. *Murr v. Wisconsin*, 137 S. Ct. 1933, 1937 (2017). The other is a three-part "ad hoc, factual inquiry" focusing on the economic impact of the regulation, whether the government action interferes with reasonable investment-backed expectations, and the action's character. *Penn Central Transp. Co. v. New York City*, 438 U.S. 104, 124 (1978). These are commonly called the *Penn Central* factors.

To the extent that Novo attempts to establish a physical taking, it misconstrues the Violation Letters as a "forced A-to-B" transfer of drugs directly to contract pharmacies. Novo Br., at 33. Such an argument makes little sense given how the 340B Program works. HHS does not acquire title to Sanofi's drugs, *United States v. Pewee Coal Co.*, 341 U.S. 114, 115-17 (1951) (plurality), obtain them for a third party, *Cedar Point*, 141 S. Ct. at 2072, or compel Novo to surrender them. *Horne v. Dep't of Agriculture*, 576 U.S. 350, 364 (2015). In other words, there is no "government-authorized invasion." *Cedar Point*, 141 S. Ct. at 2074.

Novo instead suggests in passing that Congress or HHS has authorized private third parties to buy its drugs at "confiscatory" prices, destroying their economic benefit and productive value. According to Novo, this constitutes a "per se" regulatory taking. But Novo is wrong on the facts and the law. On the law, it is unclear whether the "per se" test for regulatory takings applies in the context of personal rather than real property, as the Supreme Court has never addressed that question and has authorized only two types of per se regulatory takings to date, both dealing with land. *See, e.g.*, *Maryland Shall Issue, Inc. v. Hogan*, 963 F.3d 356, 365 (4th Cir. 2020) (declining to apply per se test to regulation banning sale of gambling machine); *McCutchen v. United States,* 145 Fed. Cl. 42, 55 (2019) (declining to apply per se test to regulation requiring gun owners to destroy bump-stock devices), *aff'd on other grounds*, 14 F.4th 1355 (Fed. Cir. 2021). In any event, on the facts, Novo has not lost all "economically viable use" associated with 340B-priced drugs. *Lucas v. South Carolina Coastal Council*, 505 U.S. 1003, 1019 (1992). Covered entities pay for what they buy to the tune of billions of dollars per year, and the average discount rate appears to be between 25 and 50 percent, not 100 percent, as Novo implies by claiming that it is "confiscatory." 82 Fed. Reg. at 1,227 n.1. This remains true even if Novo does not make any profit on 340B sales—which, to be sure, there is no evidence to support. *Sadowsky v. New York*, 732

F.2d 312, 318 (2d Cir. 1984); *Greystone Hotel Co. v. City of New York*, 13 F. Supp. 2d 524, 528 (S.D.N.Y. 1998) ("[L]ack of a profit does not establish a regulatory taking."). The relevant inquiry is whether Novo has lost, not profits, but the entire value of the property purportedly "taken." *See, e.g.*, *Rose Acre Farms, Inc. v. United States*, 559 F.3d 1260, 1268-69 (Fed. Cir. 2009). Novo has fallen short on this point.

Novo then suggests that the Violation Letters violate *Penn Central*, but it does not engage with any of the relevant factors, and even a cursory analysis demonstrates that Novo would not meet them. First, the economic impact of the 340B Program is not as drastic as Novo proclaims. Not only does Novo reap billions of dollars in annual revenue from 340B drug sales, but such sales represent about 5% of the prescription drug market and 14% of the branded drug market, leaving the vast majority of Novo's sales untouched. *Pinewood Estates of Michigan v. Barnegat Township Leveling Bd.*, 898 F.2d 347, 351 (3d Cir. 1990) ("[A] regulatory limitation on the right to use and receive profits from property will not necessarily or even usually establish that there has been a taking.") (quoting *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 434-35 (1982)); *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 539-40 (2005) (holding that the inquiry under this *Penn Central* factor turns on "the magnitude of a regulation's economic impact" and is meant to "identify regulatory actions functionally equivalent to the classic taking"). Second, "distinct, investment-backed expectations are reasonable only if they take into account the power of the state to regulate in the public interest." *Pace Res., Inc. v. Shrewsbury Twp.*, 808 F.2d 1023, 1033 (3d Cir. 1987). And the government has a "traditionally high degree of control over commercial dealings." *Lucas*, 505 U.S. at 1027. So much so that it has banned entire products from the market (in the public interest) without violating the Takings Clause. *See, e.g.*, *Andrus v. Allard*, 444 U.S. 51, 65 (1979) (eagle feathers). This reduces the extent to which Novo can reasonably expect to be

free of regulation under the 340B Program. *Id.*; *Horne*, 576 U.S. at 361. Third, based on the character of the government action, there is an obvious connection to multiple public interests, which weighs against deeming the action a taking. *Compare Penn Central*, 438 U.S. at 125, *with Penn Coal Co.*, 260 U.S. at 293; *see also Keystone Bituminous Coal Ass'n v. Duncan*, 771 F.2d 707, 716 (3d Cir. 1985). Accordingly, I find that the Violation Letters are neither a physical nor regulatory taking.

In any event, the Fifth Amendment "does not prohibit the taking of private property, but instead places [ ] condition[s] on the exercise of that power." *First English Evangelical Lutheran Church of Glendale v. Los Angeles Cnty.*, 482 U.S. 304, 314 (1987). One condition is just compensation. "When the action of the [ ] government effects a 'taking' for Fifth Amendment purposes, there is no inherent constitutional defect, provided just compensation is available." *Transmission Access Policy Study Grp. v. FERC*, 225 F.3d 667, 690 (D.C. Cir. 2000). There is no evidence in the record that Novo is not justly compensated for 340B sales or that the statutory ceiling price is insufficient in the sense of the Fifth Amendment. Another condition is public use, which is satisfied as long as a taking is not "purely private," *Midkiff*, 467 U.S. at 245; *Missouri Pac. Ry. Co. v. Nebraska*, 164 U.S. 403, 417 (1896), is "rationally related to a conceivable public purpose," *Hawaii Housing Authority v. Midkiff*, 467 U.S. 229, 241 (1984), and is not a "pretext." *Kelo*, 545 U.S. at 478. The 340B Program assists uninsured patients in affording costly medications and under-resourced providers in serving more people, decidedly public purposes even if it is also true that contract pharmacies benefit from the Program. *Monsanto*, 467 U.S. at 1014 ("The role of the courts in [determining] what constitutes a public use is extremely narrow."); *Carole Media LLC v. New Jersey Transit Corp.*, 550 F.3d 302, 309 (3d Cir. 2008)

(holding that public use requirement is met unless legislative determination is "palpably without reasonable foundation").

Finally, Novo voluntarily joined the 340B Program with full knowledge of the discount drug scheme it effected.[64] Novo claims that it only did so "with a gun to its head," because it could not access Medicare/Medicaid otherwise. It is true that the unconstitutional conditions doctrine "vindicates the Constitution's enumerated rights by preventing the government from coercing people into giving them up," including in the context of the Takings Clause. *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013). But Novo's "gun to the head' argument still fails. For one thing, financial inducement generally does not rise to the level of a taking, "as long as" a private party is "aware of the conditions" and the conditions are "rationally related to a legitimate Government interest." *Monsanto*, 467 U.S. at 1007 (conditioning license to sell a chemical on submission of data); *Minn. Ass'n of Health Care Facilities, Inc. v. Minn. Dep't of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984) (permitting "strong financial inducement"); *Garelick v. Sullivan*, 987 F.2d 913, 917 (2d Cir. 1993) ("[E]conomic hardship is not equivalent to legal compulsion for purposes of takings analysis."). More importantly, the "predicate for any unconstitutional conditions claim is that the government could not have constitutionally ordered the person asserting the claim to do what it attempted to pressure the person into doing." *Koontz*, 570 U.S. at 612. This means that, "[a]bsent the pleading of facts [or evidence] sufficient to demonstrate a 'taking,' an unconstitutional conditions doctrine claim fails." *Singer v. City of N.Y.*, 417 F. Supp. 3d 297, 327 (S.D.N.Y. 2019) (collecting cases). To the extent that Novo has not established either a physical or regulatory taking under the Violation Letters, as I find here, the

64 The *Eli Lilly* Court rejected a similar takings argument on this basis alone. 2021 WL 5039566, at *21.

unconstitutional conditions doctrine is inapplicable. Accordingly, I do not construe HHS' interpretation of the 340B statute in the Letters to raise any issues under the Takings Clause.

vii. Conclusion

Based on Congressional silence alone, Plaintiffs ask this Court to *prevent* HHS from requiring *any* contract pharmacy arrangements (though to permit them to do so voluntarily, in their own policies), *create* out of whole cloth a right for Plaintiffs to impose conditions on offers to covered entities who use multiple contract pharmacies, *limit* the definition of overcharge without any indicia of legislative intent, and deem the 340B Program an unconstitutional taking—all to dramatically size-down a drug discount scheme that Congress has expanded at least three times since 1992 and has never expressed an intention to abate. After all, HHS issued the Violation Letters only when pressed by Congress to act. *Eli Lilly*, 2021 WL 5039566, at *6 (quoting testimony from the Secretary that "We are on this one . . . . Everyone has to follow the law"). I therefore uphold the following agency interpretations in the Violation Letters: (1) the 340B statute permits contract pharmacy arrangements as a dispensing mechanism; (2) Plaintiffs' policies violate the 340B statute and they may not attach strings to 340B offers; (3) Plaintiffs' policies constitute an overcharge in the sense of § 340B; and (4) the Violation Letters are not a taking under the Fifth Amendment. However, I do not decide whether the 340B statute permits covered entities to use multiple or unlimited contract pharmacies, and I partially vacate the Letters and remand them to the agency for further consideration consistent with this Opinion.

B. Arbitrary and Capricious Challenge Under the APA

Lastly, Plaintiffs argue that the Violation Letters are arbitrary and capricious under the APA for various procedural rather than substantive reasons. *See, e.g.*, San. Opp., at 20 ("Even if

the government's reading of § 340B were correct, HRSA's May 17 letter should still be set aside because it's arbitrary and capricious."); Novo Br., at 4-6, 38. I address each in turn.

i. Reasoned Decisionmaking

First, Plaintiffs argue that HHS did not engage in reasoned decisionmaking when it issued the Violation Letters. "One of the basic procedural requirements of administrative rulemaking is that an agency must give adequate reasons for its decisions." *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016); *Pub. Citizen, Inc. v. FAA*, 988 F.2d 186, 197 (D.C. Cir. 1993) ("The requirement that agency action not be arbitrary or capricious includes a requirement that the agency adequately explain its result."). To this end, an agency "must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *State Farm*, 463 U.S. at 43. "Where the agency has failed to provide a reasoned explanation, or where the record belies the agency's conclusion, [the court] must undo its action." *Cty. of L.A. v. Shalala*, 192 F.3d 1005, 1021 (D.C. Cir. 1999) (quotations and citation omitted). "This is all that the APA requires." *Pub. Emps. for Env't Resp. v. Beaudreau*, 25 F. Supp. 3d 67, 105 (D.D.C. 2014).

The Violation Letters satisfy the APA in this regard because HHS collected data from interested parties over the course of nine months, used it to draw reasonable inferences about Plaintiffs' polices, and reached a decision on enforcement only "[a]fter . . . an analysis of the complaints [the agency] has received." AR, at 1. Looking solely to the record on hand at the time HHS acted, *SEC v. Chenery Corp.*, 318 U.S. 80, 94 (1943) ("The grounds upon which an administrative action must be judged are those upon which the record discloses that [the] action was based."); San. Opp., at 4 ("The administrative record . . . discloses everything that HRSA purportedly considered."), there are thousands of pages of complaints from covered entities

without in-house pharmacies that assert overcharges because they could not comply with Sanofi's Integrity Initiative and had to pay higher, wholesale acquisition costs for covered drugs. *See generally* AR, at 110-6,806. Some illustrative examples are below.

- Beverly Hospital says it lost $126,668 in 340B savings since Sanofi's Integrity Initiative took effect and had to pay $1,516 per unit for one of Sanofi's drugs and $3,000 per unit for another. *Id.* at 1460-63, 6,993 (attaching a purchasing spreadsheet).
- A community health center says that it no longer could afford to purchase Lantus Solostar, an insulin critical for type one diabetics. *Id.* at 1589 (attaching a screenshot from its ordering system).
- A county health service wrote to Sanofi requesting a refund after it "identified a 340B overcharge" on "8 packages . . . for a total of $3,0871.61," but Sanofi refused. *Id.* at 3158-59.
- Blue Ridge Medical Center says that Sanofi blocked 340B prices. *Id.* at 1,603.
- Lancaster Health Center says the same. *Id.* at 3,302-03 (indicating three separate drugs it tried to order at 340B prices to no avail).
- Windrose Health Network says that Sanofi charged it full price for covered drugs. *Id.* at 6,649.
- Other complaints from other covered entities reflect similar concerns. *See, e.g.*, *id.* at 139-40, 150-51, 282-83, 301-02, 321, 405-11 (attaching list of drugs Sanofi blocked), 443-49, 473-79, 848-54, 14568 (alleging losses of over $70,000), 1525-26, 1666-70, 1674-75, 3,243, 3,263.

The same is true for Novo's policy with respect to the hospitals to which it applies.

- Strong Memorial Hospital says that Novo and other manufacturers refused to offer drugs at the 340B ceiling price, resulting in overcharges of more than $2 million. *Id.* at 6,396. The hospital documented specific transactions in which Novo issued a denial, instead charging prices up to $1,291 per unit, which total several hundred thousand dollars in lost 340B savings. *Id.* at 6,417-36. These overcharges represented a fraction of "the lost opportunity and financial impact to the hospital," because its inability to purchase drugs at the ceiling price deterred it from purchasing some drugs altogether. *Id.* at 6,396.
- Several other hospitals documented specific transactions with Novo resulting in thousands of dollars of overcharges per covered entity. *Id.* at 3,14, 6,250-55, 6,296-303, 6,339-40.

Even covered entities operating their own in-house pharmacies report overcharges related to Sanofi's access restrictions.

- A clinic in Georgia says that it could only serve 40% of its 25,000 patients because six of its eleven health centers cannot operate in-house pharmacies and

the five that can are only open during business hours on weekdays. *Id.* at 7,255-56. The clinic relies on the 340B Program to provide, *inter alia*, insulin and epinephrine "for as little as $4 to $7 a dose, or even at no cost at all." *Id.*

- A provider in Michigan serving a 10,000-mile area says that it is impossible to meet its patients' needs with one in-house pharmacy. *Id.* at 7,260-62. It passes on discounts "directly to eligible patients who meet federal poverty guidelines." *Id.* It also uses 340B savings to pay for "essential health care services to its underserved rural community," including services not readily available in its area, such as addiction treatment and OB/GYN care. *Id.*
- A provider in a high-poverty area says that it expects to lose $6 million of its $8 million budget to 340B restrictions and may lay off 35 staff. *Id.* at 7,295-98.
- A provider in Arizona serves patients who would have to travel up to 180 miles each way to fill prescriptions without contract pharmacy arrangements, and as a result of Integrity Initiative, is weighing service cuts. *Id.* at 7,300-06.

The record also contains hundreds of pages of evidence detailing HHS' meetings with stakeholders who purport to be harmed by Plaintiffs.

- Avita Pharmacy has 270 covered entity clients, 98% of whom do not operate in-house pharmacies. *Id.* at 7,891-92. It says that its clients now must pay as much as $300 for insulin when they paid close to $0 before. *Id.* Avita stands to lose millions in revenue as a result, and Sanofi's Integrity Initiative "will lead to imminent harm to patients and possible site closures." *Id.*
- A contract pharmacy in West Virginia that dispenses on behalf of a covered entity says that it had "14 patients denied insulin" through the Integrity Initiative immediately after it took effect. *Id.* at 7,887.
- A tribal leader in California reports patients who must "choose between buying food and buying medications" and who consequently ended up in the emergency room. *Id.* at 7,894-97. Another tribal leader reported that his covered entity had to pay more than double for its drugs, in one case $3,400 for 100 pills, which it described as "unsustainable," and could not afford to operate its own in-house pharmacy to avoid the price increase. *Id.* at 7,894, 7,898. Yet another, observing the pharmaceutical industry's "record breaking profit[s]," stated that it is "unacceptable . . . to gauge small entities." *Id.*

As well, the record details an annual 340B survey conducted by a nonprofit trade organization. *Id.* at 7,957-63. According to the survey, 340B savings lost to Plaintiffs' policies "threaten a range of services for" 340B hospitals, with the greatest "impact [to] oncology and diabetes services." *Id.* One-third of respondents report that their hospitals could close as a result, while three-fourths of rural hospitals report that they rely on the 340B Program to keep their doors

open in the first place, and virtually all agree that some "cuts are likely." *Id.* at 7,957, 7,960-61. Sanofi's restrictions in particular will reach 97% of 340B hospitals, with most expecting to lose more than 15% of their usual savings. *Id.* at 7,962. The record likewise contains aggregate price statistics, discussed *supra*, which show a large reduction in 340B sales since Plaintiffs implemented their policies.

The Violation Letters are thus "within the bounds of reasoned decisionmaking" and grounded in the evidence. *Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2569 (2019) (assessing "[t]he evidence before the Secretary" and concluding that it "supported [his] decision"); *Fox*, 556 U.S. at 516 (observing that an agency "need not always provide a more detailed justification than what would suffice for a new policy created on a blank slate").

ii. Unexplained Inconsistency

Second, Plaintiffs argue that HHS' interpretation of the 340B statute in the Violation Letters is "legally flawed" because it has changed over time. This is the crux of their procedural APA challenge. An "unexplained inconsistency" in agency policy is "ordinarily" a "reason for holding an interpretation to be an arbitrary and capricious change." *Encino*, 136 S. Ct. at 2126; *Fox*, 556 U.S. at 515. Even so, "[a]gencies are free to change their existing policies as long as they provide a reasoned explanation for the change." *Encino*, 136 S. Ct. at 2125 (citing *Brand X.*, 545 U.S. at 981-82). To provide a "reasoned explanation," an agency must "display awareness that it is changing position" and "show that there are good reasons for the new policy." *Fox*, 556 U.S. at 515; *State Farm*, 463 U.S. at 57 ("An agency's view of what is in the public interest may change, either with or without a change in circumstances.") (quoting *Greater Bos. Television Corp. v. FCC*, 444 F.2d 841, 852 (D.C. Cir. 1971)). An agency "need not demonstrate to a court's satisfaction that the reasons for the new policy are better than the reasons for the old one," but only that "the

new policy is permissible under the statute, that there are good reasons for it, and that the agency believes it to be better." *Fox*, 556 U.S. at 515. In cases where the Supreme Court has deemed an unexplained inconsistency to exist, "the agencies had an explicit rule in place, only to later issue the opposite rule with limited or no explanation," *City of Philadelphia v. Sessions*, 280 F. Supp. 3d 579, 620 (E.D. Pa. 2017) (collecting cases), its new position is "radically different" from its prior position, *Cook Cnty. v. Wolf*, 962 F.3d 208, 230 (7th Cir. 2020) (quotations and citation omitted), or its positions are "internally inconsistent." *General Chem. Corp. v. United States*, 817 F.2d 844, 846 (D.C. Cir. 1987). This high bar is consistent with the "narrow standard of review" under which a court "is not to substitute its judgment for that of the agency." *Fox*, 556 U.S. at 513-14.

Starting from the beginning, HHS has always affirmatively answered the implicit premise of the Letters: contract pharmacies are a permissible drug delivery system under the 340B statute. Such arrangements are "part of a longstanding and unchanging [general] policy" spanning almost three decades, with which Plaintiffs complied until recently. *Dep't of Lab. v. Am. Future Sys., Inc.*, 873 F.3d 420, 428-29 (3d Cir. 2017). In fact, as early as 1996 HHS emphasized that § 340B *itself* imposes an obligation on manufacturers to fill 340B orders, regardless of whether "the [covered] entity directs the drug shipment to its contract pharmacy." 61 Fed. Reg. at 43,549; *id.* ("It is clear that *Congress envisioned* that various types of drug delivery systems would be used to meet the needs of the very diversified group of 340B covered entities."); *id.* at 43,551 ("*The statute* does not limit the covered entities' access to these avenues of drug purchasing."); *id.* at 43,555 ("[I]f a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, *the statute* directs the manufacturer to sell the drug at the discounted price."); *id.* ("If the entity directs the drug shipment to its contract pharmacy, we see no basis on

which to conclude *that section 340B* precludes this type of transaction or otherwise exempts the manufacturer from statutory compliance."). The 1996 Guidance even raised the possibility of multiple contract pharmacy sites in the future. *Id.* at 43,555.

HHS then did in 2010 what it said it was "evaluating" in 1996: it changed the number of contract pharmacy a covered entity may use to dispense 340B drugs. The agency also offered multiple reasons for doing so at that time. *See, e.g.*, 75 Fed. Reg. at 10,273 ("This would permit covered entities to more effectively utilize the 340B program and create wider patient access by having more inclusive arrangements in their communities which would benefit covered entities, pharmacies and patients served.); *id.* ("The circumstances surrounding pharmacy practice and the resources available to track transactions have changed substantially over the past decade. The AMDP provides concrete examples of the ability of covered entities to utilize multiple contract pharmacies without sacrificing program integrity. Upon review of the evidence and current circumstances, HRSA does not find sufficient basis to continue limiting contract pharmacies to a single site. The restriction has imposed its own costs by restricting the flexibility of covered entities in meeting the needs of their patients. Furthermore, pharmacy and inventory management processes are available that make utilization of more than one pharmacy readily feasible for many covered entities without increasing the risk of diversion."). Hence, if indeed HHS "chang[ed] its course" in the 2010 Guidance, *State Farm*, 463 U.S. at 42, the agency "acknowledge[d] and provide[d] an adequate explanation for its departure." *Dillmon v. NTSB*, 588 F.3d 1085, 1089-90 (D.C. Cir. 2009); *Jicarilla Apache Nation v. U.S. Dep't of Interior*, 613 F.3d 1112, 1119 (D.C. Cir. 2010).

Still more, the rationale underlying HHS' position on contract pharmacy arrangements has remained the same. The agency has always emphasized the importance of expanding patient access

to the critical services provided by covered entities while saving covered entities money. The below table provides a summary, with key parts bolded.

Interpretation	Rationale
1996 Guidance	"[B]ecause **the delivery of pharmacy services is central to the mission of** (and a legal mandate in some instances for) **these providers**, they rely on outside pharmacies to fill the need. **It would defeat the purpose of the 340B program if [ ] covered entities could not use their affiliated pharmacies in order to participate**. **Otherwise, they would be faced with the untenable dilemma of having either to expend precious resources to develop their own in-house pharmacies (which for many would be impossible) or forego participation in the program altogether.** Neither option is within the interest of the covered entities, the patients they serve, or is consistent with the intent of the law." 61 Fed. Reg. at 43,550.
2010 Guidance	"We received many comments in support of the proposal [to permit multiple contract pharmacy arrangements]. Many of these came from covered entities that participate in 340B and highlighted how their **delivery of patient care would be enhanced with a multiple contract pharmacy option**. According to these comments, some patients currently face transportation barriers or other obstacles that limit their ability to fill their prescriptions. It would be a significant benefit to patients to allow the use of more easily accessible, multiple contract pharmacy arrangements by covered entities. **This would permit covered entities to more effectively utilize the 340B program and create wider patient access by having more inclusive arrangements in their communities which would benefit covered entities, pharmacies and patients served** . . . . Upon review of the evidence and current circumstances, HRSA does not find sufficient basis to continue limiting contract pharmacies to a single site. **The restriction has imposed its own costs by restricting the flexibility of covered entities in meeting the needs of their patients**." 75 Fed. Reg. at 10,273.
Violation Letters	Noting that Sanofi risked **"restrict[ing] access" for "underserved and vulnerable populations**" during a global pandemic," and that "[e]ven for those covered entities with in-house pharmacies," **policies that "limit contract pharmacy orders would have the effect of significantly limiting access to 340B discounted drugs for many underserved and vulnerable populations** who may reside in geographically isolated areas and rely on a contract pharmacy to obtain their prescriptions."

HHS' position that at least some contract pharmacy arrangements are permissible harks all the way back to its 1994 guidance document detailing final regulations for the 340B Program. 59 Fed. Reg. 25,110, 25,112 (May 13, 1994) ("the 1994 Guidance"). There, in response to a comment suggesting that HHS should not require manufacturers to sell to contract pharmacies (or other

purchasing agents), HHS responded that such arrangements are a "customary business practice," and "limitations on sales transactions . . . could be discouraging entities from participating in the program." *Id.* at 25,111; 61 Fed. Reg. at 49,550 (stating that "a number of large organizations" used the contract pharmacy model "as early as 1993"). This is relevant because it means that HHS "issued" its contract pharmacies policy nearly "contemporaneously" with the statutory language the policy interprets. *Am. Future Sys.*, 873 F.3d at 428-29; *Schor*, 478 U.S. at 845-46 (emphasizing that "the CFTC issued the counterclaim rule concurrently in force at the time that the reparations program first took effect"). In sum, as to contract pharmacy arrangements, the Letters do not "depart from a prior policy *sub silentio* or simply disregard rules that are still on the books," *Fox*, 556 U.S. at 515; *Nixon*, 418 U.S. at 696, "casually ignore[]" a longstanding position, *Lone Mountain Processing, Inc. v. Sec'y of Labor*, 709 F.3d 1161, 1164 (D.C. Cir. 2013), or reach an "internally inconsistent" conclusion. *General Chem.*, 817 F.2d at 846. As a procedural matter, the Letters chart much the same course with much the same assumptions, interpretations, rationales, and conclusions as past agency guidance.

I make the same finding with respect to HHS' interpretation that § 340B prohibits manufacturers from attaching strings to offers to covered entities using multiple contract pharmacies. Sanofi in particular argues that HHS has long permitted manufacturers to collect data from covered entities, which is all that its Integrity Initiative seeks to do. Sanofi relies on HHS' response to a comment on its 1994 Guidance for support. 59 Fed. Reg. at 25,112. There, HHS confirmed that a manufacturer may "require [ ] covered entities to sign a contract containing only the manufacturer's normal business policies (e.g., routine information necessary to set up and maintain an account) if this is a usual business practice of the manufacturers," and permitted

"contracts that contain provisions relating to normal business activities, requests for standard information, or other appropriate contract provisions." *Id.*

However, Sanofi overstates the practice that HHS endorsed in the 1994 Guidance, while understating what its Integrity Initiative demands. The 1994 Guidance does not grant sweeping authority to manufacturers to impose whatever conditions they deem necessary on sales to covered entities. The Guidance simply clarifies that manufacturers may treat covered entities in the same way as commercial purchasers with respect to requirements *unrelated to the 340B Program*. 59 Fed. Reg. at 25,112. Critically, in doing so, the 1994 Guidance adopts various statements that foreclose the self-help measures Plaintiffs have implemented here. For instance, "[m]anufacturers may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective." *Id.* 25,113. They may not condition 340B sales on a covered entity's "submitting information related to drug acquisition, purchase, and inventory systems." *Id.* at 25,113-14. They may not "place limitations on the transactions (e.g., minimum purchase amounts) which would have the effect of discouraging entities from participating in the discount program." *Id.* And they may not "condition the offer of statutory discounts upon an entity's assurance of compliance with section 340B provisions." *Id.*

Even if Sanofi could fit its Integrity Initiative within the authority of the 1994 Guidance, the Initiative does not begin and end with data collection. Sanofi conditions the use of contract pharmacy sites *on* the adequate submission of the data it demands, and it has retained for itself the sole authority to determine whether covered entities have complied—or to change the requirements of its policy as it deems necessary. This is impermissible, regardless of whether Sanofi may lawfully collect the data itself. Likewise, while Sanofi insists that covered entities will need just five minutes each week to submit the data, calling it "ministerial," that downplays the

practical realities facing resource-strapped covered entities, some of which already report data-collection requirements with which they cannot comply. *See, e.g.*, AR., at 1,544-45, 1,547-48, 7,324-25.

HHS reaffirmed its position on offer conditions in its 2015 rule on CMPs, stating that manufacturers cannot "unilaterally overcharg[e] a covered entity based upon suspicion of diversion," rejecting a public comment recommending that "if a manufacturer has evidence a covered entity is improperly diverting a drug, it should be able to charge the covered entity a price above the 340B ceiling," reiterating that manufacturers "cannot condition the sale of a 340B drug at the 340B ceiling price" even if "they have concerns or specific evidence of possible non-compliance by a covered entity," as Plaintiffs do, and concluding that the agency "does not agree that a manufacturer could consider not selling a 340B drug at the 340B ceiling price to a covered entity based on possible non-compliance with program requirements." 82 Fed. Reg. at 1,223, 1,226. Further underscoring HHS' consistency on whether manufacturers can attach strings to 340B offers is a 2012 Notice, which the agency issued "with regard to manufacturer limitations or conditions on sales of covered outpatient drugs to eligible 340B entities." No. 2011-1.1. In the Notice, HHS reiterated that its policy prohibiting manufacturers from treating covered entities differently than other customers "is consistent with section 340B(a)(1) . . . which requires manufacturers to 'offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.'" *Id.* (quoting 42 U.S.C. § 256b(a)(1)). Even PPAs provide that a covered entity's failure to comply with Program requirements does not "relieve the Manufacturer from its obligation to conform to the pricing requirements provided in section 340B(a) of the Act and the Agreement." PPA § IV(d). Finally, as discussed at length *supra*, HHS has always defined the term overcharge to encompass

access or eligibility restrictions, not merely misprices, which firmly roots the Violation Letters in prior agency interpretations. *See, e.g.*, 75 Fed. Reg. at 57,234; 82 Fed. Reg. at 1,222-23, 1,226; 42 C.F.R. § 10.21(c)(1).

In the context of the AO, the *AstraZeneca* Court observed that HHS' position on contract pharmacies has "evolved over time" and that changing what covered entities may do necessarily has changed what manufacturers must do. 2021 WL 2458063, at *6. Plaintiffs use this as proof that the Violation Letters constitute an unexplained inconsistency in the sense of the APA, even though the court in *AstraZeneca* discussed the issue primarily to determine whether the AO was reviewable final agency action. While I agree that HHS' position has evolved throughout the years, particularly with respect to the number of permissible contract pharmacy arrangements, and with it, manufacturers' obligations under the 340B statute, I find that HHS has sufficiently explained the changes, which is the touchstone of the inquiry in the context of the APA. *See, e.g.*, *Children's Hosp. Ass'n of Texas v. Azar*, 933 F.3d 764, 773 (D.C. Cir. 2019) ("There is no unexplained inconsistency with an earlier position here. To be clear, we agree with the plaintiffs that the 2017 Rule and the 2008 Rule establish different policies. But it makes no difference. CMS explained why the statute's purposes are better fulfilled by a policy that requires consideration of payments by Medicare and private insurers."), *cert. denied*, 141 S. Ct. 235 (2020).

The *Eli Lilly* Court vacated the letter at issue in that case for unexplained inconsistencies. 2021 WL 5039566, at *22. Yet, the court did so for reasons not properly presented in Plaintiffs' motions here and different from those addressed in *AstraZeneca*: that HHS has inconsistently represented its authority *to enforce* its interpretation of the 340B statute on contract pharmacies, not that the agency has inconsistently represented the meaning of § 340B *itself*.[65] *See, e.g.*, Novo

65 Although not specifically raised by the parties, I respectfully disagree that the evidence on which the *Eli Lilly* Court relies is sufficient to permit the inference that there is an unexplained inconsistency in

Br., at 38 (arguing that HHS has not adequately "explained how its position can be reconciled with its earlier pronouncements about what *the statute requires*") (emphasis added); San. Rep. Br., at 22. On the latter point, the court did not dispute the proposition that I emphasize now: HHS "has made plain, consistently since the issuance of its 1996 contract pharmacy guidance, that the 340B statute requires manufacturers to honor [covered entities'] purchases regardless of the dispensing mechanism." *Id.* (quoting HHS brief). As the court "accepted" in *Eli Lilly*, "[HHS] has consistently espoused the view in non-binding guidance that drug manufacturers must comply with their obligations under the 340B statute regardless of the manner in which the covered entity chooses to dispense the drugs and must accommodate all contract pharmacy arrangements that the government permits." *Id.* at *22-23. As such, I do not find an unexplained inconsistency in the Violation Letters.

iii. Notice and Comment

Third, Sanofi claims that the Violation Letters are "procedurally flawed because they enforce a new legislative rule—the rule regarding contract pharmacies first announced in the [AO]—that was never subject to notice-and-comment." San. Opp., at 33. Novo goes a step further: the Letters *themselves* constitute a new legislative rule requiring a comment period. Plaintiffs are correct that an agency cannot "impose legally binding obligations . . . on regulated parties . . . that

HHS' position on its authority to enforce its interpretation of § 340B regarding contract pharmacy arrangements. For instance, the court cites HHS' position that its prior guidance documents are non-binding, which the agency maintains to this date. The court also cites an email from *Am. Hosp. Ass'n* where HHS states that it lacks "comprehensive regulatory authority" to ensure "clarity in program requirements." 2021 WL 616323, at *3. But that was "a single email from an agency official with no role in policy formulation or ultimate decision-making authority." *Id.* at *7. Further, the court cites a comment, described in a GAO Report, that the 340B statute "does not address contract pharmacy use and, therefore, there may not have been a clear statutory violation." GAO Report, No. 21-107, at 15-16. Placed in context, that comment addresses whether HHS could take action against *covered entities* for flaws in their oversight mechanisms, which is not material to the enforcement authority at issue here, exercised against *manufacturers* for their own policies. For these reasons, I would likely part ways with the *Eli Lilly* Court on this issue.

would be the basis for an enforcement action" without notice and comment rulemaking. *Nat'l Mining Ass'n v. McCarthy*, 758 F.3d 243, 252 (D.C. Cir. 2014). But their position that the Violation Letters run afoul of the APA on this basis is in any case misplaced. First, the Letters are not derivative of the AO and do not attempt to enforce it (assuming *arguendo* that the AO would constitute a new legislative rule, which HHS disputes). The Letters instead constitute separate agency action to effectuate (what HHS believes are) the commands of the 340B statute. Second, as even Sanofi appears to acknowledge, the Letters are not themselves legislative rules that are "subject to the APA's notice-and-comment requirement." San. Opp., at 36 n.14; *Bimini*, 994 F. Supp. 2d at 122-25 (same, but for an agency letter informing regulated entity that it violated a federal immigration statute and giving it time to come into compliance or else face penalties).[66]

iv. Fair Notice

Fourth, Plaintiffs argue that they did not receive "fair notice of the rule enforced in the [Violation Letters]—namely, that manufacturers must provide 340B-priced drugs to an unlimited number of contract pharmacies without condition, and that 'not allowing covered entities to reap the benefits of the 340B statute' amounts to an 'overcharge.'" San. Opp., at 31 (quoting U.S. Rep.

66 The parties do not specifically ask the Court to decide exactly what kind of agency action the Letters are. But the Letters contain features that are hallmarks of interpretive rules. *See, e.g.*, *Penn. Dep't of Hum. Servs. v. United States*, 897 F.3d 497, 505 (3d Cir. 2018) ("Interpretive rules . . . simply state what the administrative agency thinks [a] statute means, and only remind affected parties of existing duties.") (alterations omitted); *Dismas Charities, Inc. v. U.S. Dep't of Justice*, 401 F.3d 666, 682 (6th Cir. 2005) ("[A] pure legal determination of what the applicable law already is does not require notice and comment under APA § 553(b)."); *Metropolitan School District of Wayne Township v. Davila* (*Davila*), 969 F.2d 485, 492 (7th Cir. 1992) (finding Department of Education letter to be "paradigmatic case of an interpretive rule" because it "relie[d] upon the language of the statute and its legislative history" to "simply state[] what" the agency "thinks the IDEA-B requires" and to "merely explicat[e] Congress' desires," and rejecting identical procedural arguments as those suggested here). The *Eli Lilly* Court reached a similar result, holding that the letter at issue there is an "interpretive rule that is exempt from notice and comment and thus not violative of the APA on these procedural grounds" because it "clearly reflects an interpretation of the 340B statute" and is a "pure legal determination." 2021 WL 5039566, at *15. I also reject Novo's contention that the Violation Letters do not comply with HHS' "good guidance rule," which by its terms does not apply to documents "that interpret or apply the law to a specific set of facts" such as "pre-enforcement rulings" and "notices of non-compliance." 45 C.F.R. § 1.2(a).

Br., at 26). As an initial matter, as I construe them, the Letters do not expressly advance the position that Plaintiffs must ship their drugs to an unlimited number of contract pharmacy arrangements, and I do not decide that issue in this Opinion. Otherwise, Plaintiffs' contention is unpersuasive in view of § 340B's regulatory history. The 1994 Guidance mentions contract pharmacies as a common business arrangement, the 1996 Guidance raises the possibility of multiple contract pharmacy arrangements, the 2010 Guidance adopts that position, and the Violation Letters take a similar tack. Likewise, the 2012 Notice defines an overcharge in the same (broad) manner as the Violation Letters, as does the 2015 rule on CMPs and agency regulations like 42 C.F.R. § 10.21(c)(1). And HHS has long indicated to Plaintiffs that they may not (of their own accord) restrict access to 340B discounts based on fraud, abuse, or noncompliance, or single out covered entities by imposing conditions or limitations on sales of covered drugs. *See, e.g.*, 59 Fed. Reg. at 25,112-14.

v. Due Process/*Ex Parte* Adjudication

Finally, Plaintiffs argue that HHS "acted arbitrarily and capriciously by adjudicating covered entity complaints against [them] ex parte, without ever providing . . . an opportunity to see or rebut those complaints." San. Opp., at 26. Plaintiffs start by claiming that this violates due process, but that argument is without merit. Because the Letters are not a rule or part of the rulemaking process, as discussed *supra*, Plaintiffs are not entitled to the procedural protections associated with notice and comment. Neither do the Letters commence a proceeding by a covered entity against a manufacturer, such that Plaintiffs would be afforded protections under the ADR Rule. *Cf.* 42 C.F.R. § 10.21(a) (requiring service on "opposing party" and an opportunity to respond to complaint); *id.* § 10.21(f) (allowing "written response to the Petition"); 61 Fed. Reg. 65,406-01 (providing opportunity to respond to or rebut "the allegations"). Rather, the Letters

constitute an agency enforcement or pre-enforcement action, the authority for which is set forth in the authorizing statute itself. Specifically, 42 U.S.C. § 256b(d)(1)(B)(i)(IV) permits HHS to develop a price-checking system in part by "[i]nquiring into the cause of any pricing discrepancies that may be identified and either taking, or requiring manufacturers to take, such corrective action as is appropriate," and under § 256b(d)(1)(B)(v), HHS may audit manufacturers for program compliance.

Plaintiffs also claim HHS did not follow its own regulations when it issued the Letters. San. Opp., at 28 (citing *Kelly v. R.R. Ret. Bd.*, 625 F.2d 486, 491-92 (3d Cir. 1980) (holding agency action that "failed to adhere to [the agency's] own regulations . . . [as] illegal and of no effect")). Yet, Plaintiffs do not explain how, except that HHS did not comply with the ADR Rule, which again does not apply to agency-initiated actions. Nevertheless, Plaintiffs assert, they were still blindsided by the Letters. But even that is inaccurate. HHS provided initial notice of possible action when it began investigating manufacturers around August 2020. There was nothing particularly secret about the process that ensued. And in a meaningful sense, the Letters *themselves* constitute notice of future action. Plaintiffs' position is really just that they are entitled to participate in an agency's decision *whether* to initiate a pre-enforcement action. But I cannot find any case interpreting the APA to guarantee that level of process, and in any event, Plaintiffs are not without recourse, even assuming that HHS unilaterally built a one-sided record. 42 C.F.R. § 1003.100(b)(2) sets forth "appeal rights of any person subject to a [CMP]." *Id.* HHS has stated that CMPs arising out of § 340B "will be imposed pursuant to the applicable procedures contained in [§] 1003," and "[n]o further rulemaking is required to apply the procedures at [that section of the federal code] to [agency-imposed sanctions under the 340B Program]." 82 Fed. Reg. at 1,227. In addition, 42 U.S.C. § 1005.2-3 ensures trial-like procedures for manufacturers who dispute CMPs before the

OIG, and it is triggered once HHS decides to proceed with enforcement. *Id.* HHS thus did not violate due process or the APA by issuing the Violation Letters.

V. CONCLUSION

For the foregoing reasons, I **DENY** Sanofi's motion to set aside the ADR Rule and **GRANT** the Government's motion; **GRANT in part** Sanofi's and Novo's motions to set aside the Violation Letters, and **PARTIALLY VACATE** and **REMAND** the Letters for further consideration, consistent with this Opinion; and **DENY** all parties' motions as to the AO as moot. More specifically, as to the Violation Letters, I uphold HHS' assessment that Plaintiffs cannot unilaterally impose restrictions on offers to covered entities and that their policies must cease, but I vacate HHS' determination that Plaintiffs owe credits or refunds to covered entities, and face CMPs, to the extent that such determinations may depend on the number of permissible contract pharmacy arrangements under the 340B statute.

DATED: November 5, 2021

/s/ Freda L. Wolfson
Hon. Freda L. Wolfson
U.S. Chief District Judge